

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:)
) CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE)
WHOLESALE PRICE LITIGATION) Pages 1 - 98
)

TUTORIAL AND MOTION HEARING
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
July 8, 2009, 2:05 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
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<p style="text-align: right;">2</p> <p>1 A P P E A R A N C E S:</p> <p>2 FOR THE PLAINTIFFS:</p> <p>3 JOANNE M. CICALA, ESQ., JAMES P. CARROLL, ESQ.,</p> <p>4 JOCELYN NORMAN, ESQ., and KATHRYN B. ALLEN, ESQ.,</p> <p>5 Kirby McInerney, LLP, 101 College Street, Dripping Springs,</p> <p>6 Texas, 78620, for the City of New York and New York</p> <p>7 Counties.</p> <p>8 MICHAEL WINGET-HERNANDEZ, ESQ., 3112 Windsor Road,</p> <p>9 Austin, Texas, 78703, of Counsel, Kirby McInerney.</p> <p>10 FOR THE DEFENDANTS:</p> <p>11 JOHN T. MONTGOMERY, ESQ. and JOHN P. BUEKER, ESQ.,</p> <p>12 Ropes & Gray, LLP, One International Place, 02110,</p> <p>13 for Schering and Warrick.</p> <p>14 CHRISTOPHER C. PALERMO, ESQ., Kelley Drye & Warren,</p> <p>15 LLP, 101 Park Avenue, New York, New York, 10178,</p> <p>16 for Dey, Inc.</p> <p>17 ALSO PRESENT:</p> <p>18 JEFFREY FAUCL, ESQ., Assistant United States Attorney,</p> <p>19 Office of the United States Attorney, 1 Courthouse Way,</p> <p>20 Boston, Massachusetts, 02210.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">4</p> <p>1 P R O C E E D I N G S</p> <p>2 THE CLERK: In Re: Pharmaceutical Industry</p> <p>3 Average Wholesale Price Litigation, Civil Action 01-12257,</p> <p>4 will now be heard before this Court. Will counsel please</p> <p>5 identify themselves for the record.</p> <p>6 MS. CICALA: Joanne Cicala from Kirby McInerney on</p> <p>7 behalf of the City of New York and New York counties.</p> <p>8 MR. CARROLL: James Carroll from Kirby McInerney</p> <p>9 on behalf of the City of New York and New York counties.</p> <p>10 MR. BERMAN: Michael Winget-Hernandez. I'm of</p> <p>11 counsel with Kirby.</p> <p>12 MR. MONTGOMERY: John Montgomery, Ropes & Gray,</p> <p>13 for Schering and Warrick.</p> <p>14 MR. BUEKER: Good afternoon, your Honor. John</p> <p>15 Bueker, also from Ropes & Gray, for Schering and Warrick.</p> <p>16 MS. NORMAND: Jocelyn Normand from Kirby</p> <p>17 McInerney.</p> <p>18 THE COURT: For the plaintiffs?</p> <p>19 MS. NORMAND: Plaintiffs.</p> <p>20 MS. ALLEN: Kathryn Allen from Kirby McInerney,</p> <p>21 representing the City of New York and the New York counties.</p> <p>22 THE COURT: We had scheduled today a tutorial.</p> <p>23 Oh, somebody else popping up.</p> <p>24 MR. PALERMO: Good afternoon, your Honor. Chris</p> <p>25 Palermo, Kelley, Drye & Warren, on behalf of Dey and the</p>
<p style="text-align: right;">3</p> <p>1 I N D E X</p> <p>2</p> <p>3 WITNESS DIRECT CROSS REDIRECT RECROSS</p> <p>4</p> <p>5 SUMANTH ADDANKI</p> <p>6 By Mr. Bueker: 9</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">5</p> <p>1 Mylan defendants.</p> <p>2 THE COURT: Did you want to come up here?</p> <p>3 MR. PALERMO: I'm fine right here, your Honor.</p> <p>4 THE COURT: Maybe out the door? Is there anyone</p> <p>5 else who wants to introduce themselves? All right.</p> <p>6 So we had scheduled a tutorial today. Were you</p> <p>7 planning on introducing witnesses?</p> <p>8 MR. MONTGOMERY: Yes, your Honor.</p> <p>9 THE COURT: All right. Were you as well? Is this</p> <p>10 a joint?</p> <p>11 MS. CICALA: We may or may not introduce a witness</p> <p>12 in connection with the tutorial, depending on defense's</p> <p>13 presentation. We had conferred yesterday and agreed to an</p> <p>14 order, of course, pending the Court's agreement as well.</p> <p>15 THE COURT: What are you planning on?</p> <p>16 MR. MONTGOMERY: Our proposal was to present first</p> <p>17 Dr. Addanki, who is here today. Then I take it from</p> <p>18 Ms. Cicala's comment that depending on Dr. Addanki's</p> <p>19 testimony, that Mr. Devor may then testify.</p> <p>20 MS. CICALA: Yes.</p> <p>21 MR. MONTGOMERY: And that would conclude the</p> <p>22 tutorial exercise. We then discussed, subject, your Honor,</p> <p>23 to your preferences, that we would then follow the tutorial</p> <p>24 with the scheduled argument on summary judgment; and I think</p> <p>25 we've agreed on an order there, that Ms. Cicala would go</p>

<p style="text-align: right;">6</p> <p>1 first, we would go second. There is one item as to which we</p> <p>2 did not reach agreement. If the proposal that we have</p> <p>3 agreed upon is acceptable to your Honor, we ought to address</p> <p>4 that one item.</p> <p>5 THE COURT: That seems fine. My biggest concern</p> <p>6 is, as a practical matter, it's ten past 2:00, and we'll</p> <p>7 stop around 5:00, and usually I give my court reporter a</p> <p>8 break in there somewhere, which no matter how hard I try</p> <p>9 ends up being fifteen, twenty minutes. So just --</p> <p>10 MR. MONTGOMERY: We understand.</p> <p>11 THE COURT: -- that's the reality of it.</p> <p>12 MS. CICALA: That's fine, your Honor. What</p> <p>13 Mr. Montgomery is alluding to, your Honor may be aware that</p> <p>14 defendants had filed a Daubert motion in connection with</p> <p>15 Mr. Devor's proffered expert testimony, and we are of the</p> <p>16 view that the Daubert motion should be heard first in</p> <p>17 connection with today's hearing, given that in terms of</p> <p>18 Dr. Addanki's testimony, for example, Dr. Addanki is</p> <p>19 testifying on two subjects primarily.</p> <p>20 THE COURT: So you filed a Daubert?</p> <p>21 MS. CICALA: No.</p> <p>22 THE COURT: They filed it?</p> <p>23 MS. CICALA: They did.</p> <p>24 THE COURT: So let's just not do that now.</p> <p>25 MS. CICALA: Well, if I may be heard on this just</p>	<p style="text-align: right;">8</p> <p>1 the practical implications. Do you want to ask him</p> <p>2 questions that are relating to the Daubert?</p> <p>3 MS. CICALA: No. The practical implications is</p> <p>4 that your Honor is going to hear argument regarding the</p> <p>5 reliability today of Mr. Devor's conclusions. The Daubert</p> <p>6 motion makes the exact same argument.</p> <p>7 THE COURT: But it won't add to the length of the</p> <p>8 tutorial, does it?</p> <p>9 MS. CICALA: Well, I guess it would depend how the</p> <p>10 Daubert is ruled upon.</p> <p>11 THE COURT: You know what, I don't understand it</p> <p>12 well enough. Let's just get going, and at some point pop up</p> <p>13 and say, "See, this is what I mean," okay?</p> <p>14 MS. CICALA: That's fine.</p> <p>15 THE COURT: Because my biggest concern is getting</p> <p>16 through at least the two live witnesses today, and I'm not</p> <p>17 sure that -- as far as I'm concerned, this is not a mini</p> <p>18 "trial," you know, on knowledge or something like that. It</p> <p>19 really should be pretty bare bones as to how FUL is set,</p> <p>20 right?</p> <p>21 MS. CICALA: Well, actually, your Honor, yes,</p> <p>22 there's no disagreement between the parties that CMS</p> <p>23 exercised discretion when setting the FUL. There's no</p> <p>24 disagreement on that subject, so this could be very quick.</p> <p>25 The other prong, though, is the reliability of</p>
<p style="text-align: right;">7</p> <p>1 for one moment, your Honor.</p> <p>2 THE COURT: Yes.</p> <p>3 MS. CICALA: What is at issue in the Daubert is</p> <p>4 identical to the testimony of Dr. Addanki in terms of the</p> <p>5 reliability of Mr. Devor's report. So there is a complete</p> <p>6 identity of issues between the Daubert challenge and what</p> <p>7 you're going to hear from Dr. Addanki in so as far as he</p> <p>8 addresses the reliability of Mr. Devor's conclusions, and</p> <p>9 those same arguments --</p> <p>10 THE COURT: This is only a tutorial. I'm not</p> <p>11 going to accept a Daubert challenge to anyone anyway. I</p> <p>12 mean, the theory of it is, it's -- I'm sorry I missed, I</p> <p>13 didn't notice that there was a Daubert motion even pending</p> <p>14 or something to be addressed today. So you want to ask him</p> <p>15 questions that relate to the Daubert, is that it?</p> <p>16 MS. CICALA: No. We're here for two purposes,</p> <p>17 right, your Honor? We're here for the tutorial and also for</p> <p>18 the oral argument. And the Daubert motion touches on -- the</p> <p>19 tutorial -- when it comes to Mr. Devor's report, defendants</p> <p>20 make the same argument, whether it's in the tutorial or in</p> <p>21 connection with the summary judgment motions or the Daubert.</p> <p>22 THE COURT: I haven't read, I confess, I've read</p> <p>23 the motions for summary judgment, but I have not read the</p> <p>24 Daubert motion. It's catching me a little bit by surprise,</p> <p>25 so I don't even know how to rule on it. I don't understand</p>	<p style="text-align: right;">9</p> <p>1 Mr. Devor's conclusions, and that's why I raise the Daubert</p> <p>2 because that's the subject of the Daubert challenge as well.</p> <p>3 So there's an efficiency perhaps to addressing this once now</p> <p>4 while we're all here.</p> <p>5 THE COURT: I don't know. Let's just get him on</p> <p>6 and off. Let's just do this, and then I'll worry about that</p> <p>7 later because it's not even clear to me we're going to</p> <p>8 finish him.</p> <p>9 MS. CICALA: Thank you, your Honor.</p> <p>10 MR. BUEKER: Then, your Honor, the defendants</p> <p>11 would call Dr. Addanki to the stand.</p> <p>12 THE COURT: Thank you.</p> <p>13 SUMANTH ADDANKI</p> <p>14 having been first duly sworn, was examined and testified as</p> <p>15 follows:</p> <p>16 THE CLERK: Would you please state your name and</p> <p>17 spell it for the record.</p> <p>18 THE WITNESS: My name is Sumanth Addanki. That's</p> <p>19 spelled S-u-m-a-n-t-h A-d-d-a-n-k-i.</p> <p>20 DIRECT EXAMINATION BY MR. BUEKER:</p> <p>21 Q. Dr. Addanki, would you introduce yourself or</p> <p>22 reintroduce yourself, I guess, to the Court.</p> <p>23 A. Yes. I'm Sumanth Addanki. I'm an economist. I'm</p> <p>24 working on behalf of the group of defendants in this case.</p> <p>25 Q. And is it accurate to say, Dr. Addanki, that you've</p>

<p style="text-align: right;">10</p> <p>1 testified previously before this Court as an expert on</p> <p>2 pharmaceutical pricing matters?</p> <p>3 A. I have, your Honor.</p> <p>4 Q. And would you briefly remind the Court of some of your</p> <p>5 qualifications in the area of pharmaceutical pricing.</p> <p>6 A. Your Honor, I have a Ph.D. in economics, and I have</p> <p>7 spent the last almost 30 years in economic research of</p> <p>8 various kinds. And over the last two decades, I've done a</p> <p>9 great deal of research on the pharmaceutical industry,</p> <p>10 including most recently a variety of research assignments on</p> <p>11 pricing in the pharmaceutical industry. And I appeared</p> <p>12 before your Honor in connection with the MDL about two and a</p> <p>13 half years ago in December of 2006.</p> <p>14 THE COURT: Well, have you done any of this work</p> <p>15 on pricing in a nonlitigation context?</p> <p>16 THE WITNESS: I've done some work on pricing in a</p> <p>17 nonlitigation context, and certainly a lot of it in research</p> <p>18 having nothing to do with AWP litigation.</p> <p>19 THE COURT: Is it other litigation?</p> <p>20 THE WITNESS: Sometimes litigation and sometimes</p> <p>21 other contested proceedings of arbitrations or other</p> <p>22 proceedings of that kind.</p> <p>23 Q. And, Dr. Addanki, have you prepared a PowerPoint</p> <p>24 presentation to help you assist in presenting your tutorial</p> <p>25 today?</p>	<p style="text-align: right;">12</p> <p>1 were reasonably representative of the larger group of drugs</p> <p>2 for which CMS sets FULs. And those nine drugs had 31 FULs</p> <p>3 associated with them, and those are in fact the FULs that I</p> <p>4 studied, your Honor.</p> <p>5 Q. So the Court has some idea of where we're headed, would</p> <p>6 you summarize briefly for the Court at this point the</p> <p>7 conclusions that you reached as an economist based on your</p> <p>8 examination of the data that showed how CMS set FULs.</p> <p>9 A. Yes, of course. Although CMS's regulation specifies</p> <p>10 that the FUL shall be set as 150 percent of the lowest</p> <p>11 published price available, what I find from my analysis,</p> <p>12 your Honor, is that in the overwhelming majority of cases,</p> <p>13 CMS did not follow that rule. Rather, what they did was,</p> <p>14 using a variety of market-risk intelligence, CMS exercised</p> <p>15 its discretion on a case-by-case basis and chose FULs and</p> <p>16 maintained FULs that were higher than the simple rule would</p> <p>17 have predicted.</p> <p>18 And, finally --</p> <p>19 THE COURT: Excuse me. What time period are we</p> <p>20 talking about?</p> <p>21 THE WITNESS: We're talking about the period</p> <p>22 from -- I think FULs ranged from -- set from 1996 to about</p> <p>23 2005, your Honor.</p> <p>24 THE COURT: So you looked at all the --</p> <p>25 THE WITNESS: The entire, exactly, all FULs that</p>
<p style="text-align: right;">11</p> <p>1 A. I have.</p> <p>2 MR. BUEKER: Your Honor, I shared a copy of this</p> <p>3 with counsel for plaintiffs this morning, and they have a</p> <p>4 copy. I have several copies for the Court and the clerk.</p> <p>5 THE COURT: I look forward to them. I don't know</p> <p>6 what a hearing would be without them.</p> <p>7 MR. BUEKER: And I think it's also up on the</p> <p>8 screen. And Dr. Addanki has the mouse to be able to control</p> <p>9 it as he sees fit, but I thought the PowerPoint and hard</p> <p>10 copy helped.</p> <p>11 Q. Would you, Dr. Addanki, just kind of briefly describe</p> <p>12 what you've been asked to do in connection with this case.</p> <p>13 A. Primarily my assignment had two parts, your Honor. The</p> <p>14 first part was to analyze how CMS actually sets FULs; and</p> <p>15 the second part was, in light of the results of my analysis</p> <p>16 of how CMS sets FULs, to evaluate the plaintiffs' claims</p> <p>17 that had the defendants reported alternative prices to the</p> <p>18 compendia, that the FULs set by CMS would have been</p> <p>19 different as a result, would have been lower as a result.</p> <p>20 Q. And so it's clear for the Court, did you look at the</p> <p>21 nine drugs that were at issue in this proceeding and examine</p> <p>22 how CMS set the FULs for those nine drugs?</p> <p>23 A. Yes, I did. I understand that nine drugs were selected</p> <p>24 for this first phase of study, and that those nine drugs,</p> <p>25 the parties have agreed and CMS witnesses have testified,</p>	<p style="text-align: right;">13</p> <p>1 were set during the period that I understood to have been</p> <p>2 identified as the relevant period.</p> <p>3 MR. BUEKER: And to jump in here, your Honor, I</p> <p>4 think in CMO 33, what you did was set a relevant period,</p> <p>5 which was 1997 to 2005, and actually direct the parties to</p> <p>6 choose five drugs apiece to look at as a targeted bit of</p> <p>7 discovery, and that's been the focus of this presentation.</p> <p>8 A. And my final conclusion was, in light of what I found</p> <p>9 about how CMS had set the FULs that I've just explained to</p> <p>10 you, that I've just described to you, the contention, the</p> <p>11 idea, the proposition that had the defendants reported</p> <p>12 transactions prices rather than undiscounted list prices,</p> <p>13 that the FULs set by CMS would have been lower, that makes</p> <p>14 no economic sense in light of what I found about how CMS</p> <p>15 sets the FULs.</p> <p>16 Q. Before we return to kind of what you found, would you</p> <p>17 just describe for the Court your methodology. What did you</p> <p>18 do to arrive at your conclusions?</p> <p>19 A. Certainly. I start, your Honor, with the regulation</p> <p>20 itself that sets forth how the FULs shall be set. And I've</p> <p>21 got it up on the slide here. It says that "CMS is required</p> <p>22 to establish a FUL if there are at least three suppliers of</p> <p>23 A-rated or therapeutically equivalent products." And it</p> <p>24 further says that "The FUL is to be set at 150 percent of</p> <p>25 the lowest published price for the 100-count package size or</p>

<p style="text-align: right;">14</p> <p>1 the most commonly-available package size."</p> <p>2 So it really sets forth a pretty straightforward</p> <p>3 rule: If there are three or more alternatives available,</p> <p>4 set the FUL at 150 percent of the lowest published price</p> <p>5 available.</p> <p>6 I further understand that the sources that CMS</p> <p>7 refers to for the published prices are the three pricing</p> <p>8 compendia, Medi-Span, Blue Book, which is FDB's publication,</p> <p>9 and Red Book.</p> <p>10 Q. Would you walk the Court through, Dr. Addanki, the</p> <p>11 steps you took to determine whether CMS in practice actually</p> <p>12 followed this rule.</p> <p>13 A. Yes. One of the things we're helped by in this whole</p> <p>14 exercise is that when CMS sets a FUL, your Honor, it issues</p> <p>15 a letter of transmittal to state Medicaid agencies informing</p> <p>16 the Medicaid agencies that a FUL has been changed or set.</p> <p>17 And what that transmittal includes is information about the</p> <p>18 drug at issue, the drug for which the FUL is being set, the</p> <p>19 period during which that FUL will be effective. And it also</p> <p>20 sets forth in the transmittal the month during which the</p> <p>21 prices that CMS consulted in setting its FULs, the prices</p> <p>22 that CMS relied upon in setting it's FUL, were current. So</p> <p>23 I'll refer to that as the current month from now on.</p> <p>24 Now, I want to note that CMS does not specify</p> <p>25 which price it used as the basis for the FUL that it's</p>	<p style="text-align: right;">16</p> <p>1 THE WITNESS: That's right.</p> <p>2 THE COURT: Because AMPs are not published?</p> <p>3 THE WITNESS: That's right, exactly.</p> <p>4 THE COURT: Are they published internally to the</p> <p>5 agency?</p> <p>6 THE WITNESS: Within CMS?</p> <p>7 THE COURT: Yes. Are they published in any kind</p> <p>8 of format like a Blue Book or something internal to the</p> <p>9 agency?</p> <p>10 THE WITNESS: If they are, I'm not aware of it,</p> <p>11 your Honor. I don't know.</p> <p>12 THE COURT: So at least based on your review of</p> <p>13 the documents, when CMS refers to published prices, they're</p> <p>14 not picking up AMP in any way?</p> <p>15 THE WITNESS: I understand that when CMS refers to</p> <p>16 published prices, they're speaking about these three types</p> <p>17 of prices in the three compendia that I mentioned.</p> <p>18 Q. So you were walking the Court through the steps you</p> <p>19 took to find the universe of published prices CMS had before</p> <p>20 it.</p> <p>21 A. Yes. The first step is to identify all of the NDCs</p> <p>22 whose prices might be relevant to this exercise because</p> <p>23 there were therapeutic equivalents that were available at</p> <p>24 the time, your Honor. And in doing that, I followed a</p> <p>25 couple of steps, and I'll run us through them very quickly,</p>
<p style="text-align: right;">15</p> <p>1 issuing. It does, however, say in the transmittal what</p> <p>2 compendium the price came from. So it would specify whether</p> <p>3 it was Blue Book, which was the First DataBank price, or</p> <p>4 Red Book or Medi-Span. It doesn't say which price it used</p> <p>5 from there. It does tell you which month those prices were</p> <p>6 current in.</p> <p>7 Q. So just so we're clear, how is it that looking at the</p> <p>8 transmittal you determine what the universe of prices CMS</p> <p>9 had before it when it set the FUL is?</p> <p>10 A. Well, the transmittal only gives you the first step in</p> <p>11 that process. Again, going back to what the regulation</p> <p>12 says, we need to identify all of the therapeutically</p> <p>13 equivalent products available at the time during that</p> <p>14 current month and identify the prices for such products that</p> <p>15 were valid during that current month. And that's the</p> <p>16 process that I can quickly walk us through, your Honor.</p> <p>17 THE COURT: So when you say published prices, what</p> <p>18 are we talking about, AWP?</p> <p>19 THE WITNESS: Yes, your Honor.</p> <p>20 THE COURT: WAC, and what else?</p> <p>21 THE WITNESS: And direct price.</p> <p>22 THE COURT: And the direct price.</p> <p>23 THE WITNESS: The direct price, those are the</p> <p>24 three prices.</p> <p>25 THE COURT: But not AMPs?</p>	<p style="text-align: right;">17</p> <p>1 and I'm happy to explain any of them in more length if you'd</p> <p>2 like, your Honor.</p> <p>3 The first step was that in FDB, in First DataBank</p> <p>4 data, there actually is a field called the GCN sequence</p> <p>5 number which identifies whether a particular NDC belongs to</p> <p>6 a particular generic grouping or not. So that's my starting</p> <p>7 point. I identify all the NDCs that correspond to the</p> <p>8 GCN -- I'm sorry for the alphabet soup, your Honor, but</p> <p>9 that's the nature of this industry -- that correspond to the</p> <p>10 GCN to which the FUL applies. But because FDB does not have</p> <p>11 necessarily all of the NDCs that might be relevant in its</p> <p>12 own database, I then look at how those NDCs that FDB</p> <p>13 identified as being in the GCN were described in the</p> <p>14 Red Book and Medi-Span data, capture the descriptions of</p> <p>15 these NDCs that appear in the Medi-Span and Red Book data,</p> <p>16 and then search those compendia for other NDCs that have the</p> <p>17 same description. And I've got up here, your Honor --</p> <p>18 THE COURT: You told me, but GCN is again?</p> <p>19 THE WITNESS: It's Generic Code Number.</p> <p>20 THE COURT: As opposed to NDC?</p> <p>21 THE WITNESS: As opposed to NDC, yes.</p> <p>22 THE COURT: Is it for branded?</p> <p>23 THE WITNESS: No. NDC is just the National Drug</p> <p>24 Code. It's just a code that identifies --</p> <p>25 THE COURT: So what's generic code number?</p>

<p style="text-align: right;">18</p> <p>1 THE WITNESS: The generic code number is the</p> <p>2 grouping of the generic formulations that can be considered</p> <p>3 to be substituted for one another and that pharmacies can</p> <p>4 substitute for one another when a prescription is presented.</p> <p>5 Q. So maybe I can clear this up with a question. Would</p> <p>6 all, Dr. Addanki, Clonazepam, for example, NDCs have the</p> <p>7 same GCN?</p> <p>8 A. To the extent that they appear in FDB, your Honor, the</p> <p>9 GCN code would say it's the Clonazepam GCN. Of course,</p> <p>10 those that don't appear in the First DataBank compendium but</p> <p>11 only appear in Red Book or Medispan won't have it because</p> <p>12 those compendia don't have a GCN field. But we are able to</p> <p>13 identify the NDCs that would need to be added from those</p> <p>14 compendia by means of the descriptions, and the slide I've</p> <p>15 got up here, your Honor, shows the descriptions that applied</p> <p>16 to the Clonazepam .5 milligram GCN.</p> <p>17 Q. Dr. Addanki, once you had a comprehensive list of all</p> <p>18 of the NDCs that needed to be considered, what did you do</p> <p>19 next?</p> <p>20 A. Well, again, if you recall, the regulation says that we</p> <p>21 have to restrict this to prices for A-rated therapeutic</p> <p>22 equivalents. So the next step was to make sure that I did</p> <p>23 not have in there any NDCs that were not A-rated therapeutic</p> <p>24 equivalents, and the basic source for that is the Orange</p> <p>25 Book, the FDA's Orange Book. And by direct reference to the</p>	<p style="text-align: right;">20</p> <p>1 handle the data in slightly different ways, they each have</p> <p>2 their own ways of identifying when a posting is valid and</p> <p>3 when it's been superseded.</p> <p>4 THE COURT: You say FUL was set on a certain set</p> <p>5 of numbers. Is it that way forever, or does the agency</p> <p>6 adjust them quarterly, yearly?</p> <p>7 THE WITNESS: Oh, the agency can adjust FULs --</p> <p>8 THE COURT: I know they can, but what I'm</p> <p>9 saying --</p> <p>10 THE WITNESS: -- and do --</p> <p>11 THE COURT: And do.</p> <p>12 THE WITNESS: -- and do, from the data that I have</p> <p>13 seen, at extremely variable intervals. It can be a matter</p> <p>14 of weeks and months, it can be a matter of years before they</p> <p>15 decide to change a FUL.</p> <p>16 THE COURT: And we don't know what alerts them to</p> <p>17 make a change?</p> <p>18 THE WITNESS: Well, the data that are available to</p> <p>19 them are current data, the electronic data, the current</p> <p>20 data. So at least the one thing, as far as I know, that is</p> <p>21 not preventing them from making any change is, or not</p> <p>22 impeding them from making any change, is availability of</p> <p>23 up-to-date data. But beyond that, I don't know what it is</p> <p>24 that prompts them to make a change for some FULs --</p> <p>25 THE COURT: But there's no regulation or policy or</p>
<p style="text-align: right;">19</p> <p>1 Orange Book and using data that the compendia gathered from</p> <p>2 the Orange Book, I was able to discard from the set any NDCs</p> <p>3 that were not A-rated therapeutic equivalents.</p> <p>4 Q. What did you do next?</p> <p>5 A. The next step was, of course, to then go and gather the</p> <p>6 prices, your Honor, for these NDCs, these A-rated</p> <p>7 therapeutic equivalents; and the three sources that I used</p> <p>8 were the FDB, First DataBank data, the Red Book, and</p> <p>9 Medi-Span.</p> <p>10 Now, I can't actually show you examples of the</p> <p>11 data because the data I used were electronic, but some of</p> <p>12 these electronic data also do appear in hard-copy form, and</p> <p>13 I've at least got a couple of those hard-copy examples here</p> <p>14 on the slide. But the data that we used were electronic</p> <p>15 data that the compendia publishers provide.</p> <p>16 Q. Dr. Addanki, are those the same sources of information</p> <p>17 as are set forth in the CMS transmittal?</p> <p>18 A. Yes.</p> <p>19 Q. And the prices that you collected, what prices did you</p> <p>20 collect?</p> <p>21 A. We collected the direct price, the WAC, and the AWP.</p> <p>22 THE COURT: And how often are they adjusted?</p> <p>23 THE WITNESS: It depends, your Honor. The</p> <p>24 compendia record all of the price postings that were made</p> <p>25 for a particular NDC. Because the different compendia</p>	<p style="text-align: right;">21</p> <p>1 practice that you could discern? It was catch-as-catch-can?</p> <p>2 THE WITNESS: It appears to be. It appears to be,</p> <p>3 and I'll get into that in a little more detail as I describe</p> <p>4 the results.</p> <p>5 Q. And, Dr. Addanki, once you had this list of prices</p> <p>6 compiled for all the relevant NDCs, what did you do?</p> <p>7 A. Well, the last stage was, in identifying the prices</p> <p>8 that would have been available from which to set the FUL,</p> <p>9 was to eliminate any prices that were obsolete or invalid</p> <p>10 because they were superseded, or invalid because the NDC</p> <p>11 itself had been declared obsolete. So it was really a</p> <p>12 question of winnowing out prices that could not have been or</p> <p>13 shouldn't have been used as a basis for a FUL; and that</p> <p>14 gives us, finally, an array of prices, your Honor, and I'll</p> <p>15 show you an example of it.</p> <p>16 But the other thing I did do was, wherever I had a</p> <p>17 FUL that CMS documents, testimony, or the CMS witnesses had</p> <p>18 made reference to, to the extent possible, I confirmed the</p> <p>19 results of my analysis with whatever information I could</p> <p>20 find from CMS.</p> <p>21 Q. Now, Dr. Addanki, you mentioned you had an example of</p> <p>22 the resulting array.</p> <p>23 A. Yes.</p> <p>24 THE WITNESS: Your Honor, if I may step down, and</p> <p>25 I've got a poster board with it on it?</p>

<p style="text-align: right;">22</p> <p>1 THE COURT: Yes.</p> <p>2 THE WITNESS: I'm not sure if you can see it from</p> <p>3 over there, your Honor.</p> <p>4 THE COURT: I have it here.</p> <p>5 MR. BUEKER: It's on Slide 17, your Honor.</p> <p>6 THE WITNESS: It's the Clonazepam .5 milligrams.</p> <p>7 It's the one, actually, I've been talking about as the</p> <p>8 example throughout so far. And this is the FUL that was set</p> <p>9 in November, 2001, to be in effect from January, 2002, and</p> <p>10 it was based on prices that were current as of April, 2001.</p> <p>11 And all that information is from the transmittal letter.</p> <p>12 The FUL was set, your Honor, at .2455, which is</p> <p>13 24.55 cents per pill. And I've got the prices arrayed here</p> <p>14 that were the results of my analysis of identifying all of</p> <p>15 the prices that CMS could have used, based on the</p> <p>16 regulation, and arrayed in order, in diminishing order of</p> <p>17 price. And as we can see, the FULs that they picked matches</p> <p>18 this band in orange: Actavis which had a WAC of .1637,</p> <p>19 resulting in a FUL, if you adjust for the rounding problem,</p> <p>20 of .2455. And I did verify this with a CMS document, and</p> <p>21 indeed Actavis was called Purepak at that time, and the FUL</p> <p>22 was in fact based on exactly that NDC.</p> <p>23 What I'd like to point out, though, is that CMS</p> <p>24 did not elect to set the FUL at 150 percent of the lowest</p> <p>25 published price here. The lowest published price was</p>	<p style="text-align: right;">24</p> <p>1 this and said exactly as Dr. Addanki has said; that when CMS</p> <p>2 was exercising its discretion to pass over lower published</p> <p>3 prices, what it was doing was balancing two competing</p> <p>4 concerns, the first being cost savings, obviously pushing it</p> <p>5 lower, but at the same time access. And so when asked</p> <p>6 repeatedly about why CMS passed over lower published prices,</p> <p>7 the answer was "access."</p> <p>8 THE COURT: It went to the highest price, not to</p> <p>9 the lowest. I mean --</p> <p>10 THE WITNESS: No. Your Honor, there are a lot of</p> <p>11 prices higher than that that they could have gone to.</p> <p>12 There's a full array of prices, your Honor. It's just that</p> <p>13 the colors start only with the one that they picked. So,</p> <p>14 for instance, they could have used the UDL WAC of 17 cents.</p> <p>15 THE COURT: Oh, I see. Oh, I'm sorry. Then I</p> <p>16 misunderstood. So the yellow is only --</p> <p>17 THE WITNESS: It's only highlighting the ones</p> <p>18 below.</p> <p>19 THE COURT: I see, I see. So all of it --</p> <p>20 THE WITNESS: All the prices are valid prices that</p> <p>21 were available to CMS.</p> <p>22 THE COURT: On both side of this?</p> <p>23 THE WITNESS: Exactly.</p> <p>24 THE COURT: I see, I see.</p> <p>25 THE WITNESS: So they chose the orange one, but</p>
<p style="text-align: right;">23</p> <p>1 Major's WAC of .0799, which would have resulted in a FUL of</p> <p>2 slightly under 12 cents, your Honor. They passed over that</p> <p>3 as well as another Teva NDC, a direct price of .0989, which</p> <p>4 would have resulted in a FUL of slightly under 15 cents.</p> <p>5 They elected to set a FUL that was quite a bit higher,</p> <p>6 about --</p> <p>7 THE COURT: Was anyone asked why point-blank about</p> <p>8 this spread here, this cluster?</p> <p>9 THE WITNESS: It was a question of access, your</p> <p>10 Honor, availability.</p> <p>11 THE COURT: No, no, did someone ask someone at CMS</p> <p>12 who's responsible about this cohort, why they picked the</p> <p>13 highest number rather than the lowest number?</p> <p>14 MR. BUEKER: I can answer that question most</p> <p>15 directly, I think, your Honor. The answer is twofold:</p> <p>16 First, the individual who actually was responsible for</p> <p>17 setting this was a woman by the name of Cindy Bergen, who we</p> <p>18 were denied under Touhy the opportunity to depose, number</p> <p>19 one. However, Sue Gaston, who we were allowed to depose,</p> <p>20 was asked about this particular FUL --</p> <p>21 THE COURT: Who is she?</p> <p>22 THE WITNESS: Sue Gaston is another individual at</p> <p>23 CMS who set FULs during the relevant period of time,</p> <p>24 actually worked side by side with Ms. Bergen and looked</p> <p>25 at -- it's Exhibit 5 to Ms. Gaston's deposition -- looked at</p>	<p style="text-align: right;">25</p> <p>1 they passed over the seven ones that are highlighted in</p> <p>2 yellow.</p> <p>3 And the one last thing I'd like to point out on</p> <p>4 this chart is, the data are not shown on this chart, your</p> <p>5 Honor, but the Teva NDC that I just mentioned which has the</p> <p>6 direct price of .0989 was a very large NDC in terms of</p> <p>7 sales. It accounted for well over 40 percent of the</p> <p>8 reimbursement under Medicaid throughout this relevant period</p> <p>9 for this drug, for Clonazepam .05 milligram.</p> <p>10 Q. Dr. Addanki, do you have another example of the results</p> <p>11 of your analysis showing another one of these arrays?</p> <p>12 THE COURT: Can I ask you, though, did you see any</p> <p>13 situations where suppose every -- what were the AMPs for</p> <p>14 these drugs?</p> <p>15 THE WITNESS: The Teva AMP for this direct price,</p> <p>16 your Honor, is slightly under 3 cents.</p> <p>17 THE COURT: And was that roughly where everybody</p> <p>18 else was?</p> <p>19 THE WITNESS: I don't know what everyone's AMPs</p> <p>20 were.</p> <p>21 THE COURT: Three cents, 5 cents, 4 cents?</p> <p>22 THE WITNESS: I don't know, your Honor.</p> <p>23 THE COURT: Suppose they were all sort of in that</p> <p>24 range, you know, 4 cents, 3 cents, 6 cents, and all lowest</p> <p>25 were there, did you see any examples like that where they</p>

<p style="text-align: right;">26</p> <p>1 would then just go to a higher price? In other words, if</p> <p>2 everybody told the truth that it's AMP, would it have</p> <p>3 shifted the dynamic downward?</p> <p>4 THE WITNESS: If everyone told them what their</p> <p>5 AMPs were?</p> <p>6 THE COURT: Their theory is that a WAC is an AMP.</p> <p>7 THE WITNESS: Okay.</p> <p>8 THE COURT: If everyone in this group had actually</p> <p>9 reported the AMPs in your yellow and orange highlighting,</p> <p>10 would that have shifted the price down?</p> <p>11 THE WITNESS: Based on what I see CMS doing, your</p> <p>12 Honor -- and I'm going to talk about this in more detail --</p> <p>13 based on what I see CMS doing in setting the FULs, no.</p> <p>14 THE COURT: Did anyone ask that? In other words,</p> <p>15 I understand what you're saying here is that within the</p> <p>16 range between 16 cents and 7 cents, they picked the</p> <p>17 16 cents seemingly randomly, that they picked a number that</p> <p>18 wasn't the rock bottom but was near the bottom. But suppose</p> <p>19 the nearer the bottom was a lot lower, it was in the</p> <p>20 vicinity of 3 or 4 cents, let's say, for all of these, would</p> <p>21 that have shifted the paradigm down?</p> <p>22 THE WITNESS: That's a very interesting question</p> <p>23 you ask. If I can reask the question, let me see if I've</p> <p>24 got your question right.</p> <p>25 THE COURT: I'm sure you can think about it in a</p>	<p style="text-align: right;">28</p> <p>1 what they do in any given situation.</p> <p>2 THE WITNESS: You cannot predict it if you believe</p> <p>3 that all they look at is published prices, that's correct.</p> <p>4 THE COURT: Well, we know they're flat out</p> <p>5 violating this regulation. So assume you're right that they</p> <p>6 do that systematically. I don't know what I do with that</p> <p>7 legally, but assume you're right, they flat out violate the</p> <p>8 regulation systematically. And it may be for benign</p> <p>9 purposes, but they violate it. So what you're saying here</p> <p>10 is, you can't really predict if everybody had truthfully</p> <p>11 reported their WACs so that that was the lowest published</p> <p>12 price, so instead of the published price being 16 cents, it</p> <p>13 was 5 cents, and the next one down is 4 cents, and the next</p> <p>14 one -- you couldn't predict what they would do with that.</p> <p>15 Is that what you're trying to --</p> <p>16 THE WITNESS: What I'm saying is that without</p> <p>17 knowing what other intelligence they were using to make the</p> <p>18 determination, your Honor, that in this case, I'm not going</p> <p>19 to go to 12 cents, I'm not going to go to 15 cents, I'm not</p> <p>20 going to go to 18 cents; I'm going to go to 25 cents.</p> <p>21 Whatever intelligence was there -- and the testimony is that</p> <p>22 they gathered a lot of intelligence -- whatever intelligence</p> <p>23 was telling them that "In order to satisfy my access and</p> <p>24 cost requirements objectives, here's what I'm going to set</p> <p>25 the FUL," that intelligence is still out there; and whether</p>
<p style="text-align: right;">27</p> <p>1 more sophisticated way, but suppose they have the AMPs</p> <p>2 instead of the WACs, so that these numbers are all in the</p> <p>3 range of 3, 4, 5 cents, and they're all at the bottom there,</p> <p>4 wouldn't that have at least shifted it down a few pennies?</p> <p>5 THE WITNESS: There are instances where -- okay,</p> <p>6 in this instance, your Honor, the difference between the FUL</p> <p>7 that they set and the FUL that they could have set based on</p> <p>8 just blind application of the reg, and they certainly were</p> <p>9 entitled to have set based on its being a published price,</p> <p>10 is only a factor of two. It's 12 cents to 25 cents. There</p> <p>11 are cases where it's --</p> <p>12 THE COURT: That's actually huge. I mean --</p> <p>13 THE WITNESS: But there are cases where it's much</p> <p>14 bigger. There are cases where it's much bigger than that,</p> <p>15 where you could have had a two order of magnitude difference</p> <p>16 between the FUL that was available to them under the reg and</p> <p>17 based on the published prices that were out there and the</p> <p>18 one that they actually picked was way up there. There is no</p> <p>19 particular pattern to either the percentage or the dollar or</p> <p>20 cent difference between where they could have gone and where</p> <p>21 they actually went.</p> <p>22 THE COURT: Essentially -- I'm trying to</p> <p>23 understand -- you're thinking is pretty much random --</p> <p>24 THE WITNESS: No.</p> <p>25 THE COURT: -- in the sense that you can't predict</p>	<p style="text-align: right;">29</p> <p>1 people are reporting AMPs or people are reporting ASPs or</p> <p>2 people are reporting whatever they're reporting, that</p> <p>3 intelligence doesn't go away.</p> <p>4 THE COURT: Well, did any of these folks say in</p> <p>5 the depositions that they actually looked at the AMP?</p> <p>6 THE WITNESS: I don't recall whether anyone said</p> <p>7 they looked at the AMP or not.</p> <p>8 THE COURT: So as far as when you did your review,</p> <p>9 you personally were only looking at what happened with</p> <p>10 respect to the published prices in the various publications.</p> <p>11 You weren't really looking at how it correlated with AMPs.</p> <p>12 THE WITNESS: Well, I did look at those AMPs that</p> <p>13 I had, and I did find that, for instance, this Teva NDC here</p> <p>14 had an AMP that was about -- sorry, go ahead.</p> <p>15 THE COURT: And which Teva were you just pointing</p> <p>16 to?</p> <p>17 THE WITNESS: The Teva direct price of .0989</p> <p>18 THE COURT: Right, because that was the .03.</p> <p>19 THE WITNESS: Yes, about --</p> <p>20 THE COURT: A third.</p> <p>21 THE WITNESS: Right.</p> <p>22 THE COURT: So what you don't know is, if you were</p> <p>23 to correlate this all with AMPs, whether or not, A, the</p> <p>24 agency did that, or, B, if we were to do that, you would say</p> <p>25 it would be guessing as to what they would have done with</p>

<p style="text-align: right;">30</p> <p>1 that?</p> <p>2 THE WITNESS: Well, in particular because there</p> <p>3 are clearly other data that they are relying on that you</p> <p>4 cannot tell from here just from published prices, you cannot</p> <p>5 tell what it is they were relying on to say, "This is not</p> <p>6 the right data, this is not the right data. This is the</p> <p>7 right --"</p> <p>8 THE COURT: So when this was asked, what did she</p> <p>9 say?</p> <p>10 MR. BUEKER: This? Your Honor, again, she said</p> <p>11 she was balancing two competing --</p> <p>12 THE COURT: But how did she come up with this? Is</p> <p>13 there a formula? Did she throw up a coin in the air, and if</p> <p>14 it's heads, it's No. 6, and tails it's the bottom? What did</p> <p>15 she do?</p> <p>16 MR. BUEKER: I think the testimony in the record,</p> <p>17 your Honor, is, they called manufacturers, they called</p> <p>18 wholesalers. There is no dispute -- whether or not she</p> <p>19 actually looked at AMP, there's no dispute that CMS had --</p> <p>20 THE COURT: Excuse me, excuse me. Did she say she</p> <p>21 looked at the AMP?</p> <p>22 MR. BUEKER: She did not, your Honor.</p> <p>23 THE COURT: She said she didn't look.</p> <p>24 MR. BUEKER: She said she did not look at the AMP.</p> <p>25 But they certainly had -- and there's an instance later --</p>	<p style="text-align: right;">32</p> <p>1 ignore a lot of NDCs, some a fewer NDCs, big NDCs, small</p> <p>2 NDCs. The gap between where they could have been and where</p> <p>3 they will actually choose the FUL can be very big, smaller.</p> <p>4 It's very, very variable.</p> <p>5 However, the one thing that is systematic is, they</p> <p>6 go up. They set the FUL higher than 150 percent.</p> <p>7 THE COURT: So you're saying, of these nine drugs</p> <p>8 and these 31 NDCs, not once do they go to the bottom number?</p> <p>9 THE WITNESS: In only two cases out of 31 FULs do</p> <p>10 I find the situation where a FUL was set at the lowest</p> <p>11 published price, and during the period in which the FUL was</p> <p>12 in effect, there were no published prices that appeared that</p> <p>13 could have caused that FUL to be lower. In every other, 29</p> <p>14 cases out of 31, your Honor, either there was a lower price</p> <p>15 available at the time it was set, or during the time the FUL</p> <p>16 was in effect; and very often for a very substantial portion</p> <p>17 of that period during which the FUL was in effect, you had</p> <p>18 lower published prices that could have brought the FUL much</p> <p>19 lower, and CMS elected not to do it.</p> <p>20 So I guess going back to your question, what I</p> <p>21 conclude from this is that -- you know, I'm assuming that</p> <p>22 they're doing their jobs, and their objectives I know are</p> <p>23 twofold.</p> <p>24 THE COURT: Well, it's a legal question. They</p> <p>25 seem to be violating the regulations.</p>
<p style="text-align: right;">31</p> <p>1 THE COURT: We can argue this at the motion later.</p> <p>2 So part of your analysis is -- you essentially</p> <p>3 didn't look at AMPs or any correlation. You're just simply</p> <p>4 saying it's not clear why they would pick any particular</p> <p>5 price because you have to know about that price at that</p> <p>6 point in time and that regulator, and there's no regulation</p> <p>7 or policy or practice that would help us?</p> <p>8 THE WITNESS: I think it goes a little beyond</p> <p>9 that, your Honor. I think it goes a little beyond that in</p> <p>10 the sense that -- and perhaps I should just summarize my</p> <p>11 results so I can put this in sort of some context, but I'm</p> <p>12 happy to just give you the headline right now, and then we</p> <p>13 can talk about it more in detail.</p> <p>14 THE COURT: Do you teach as well?</p> <p>15 THE WITNESS: I have and sometimes do.</p> <p>16 THE COURT: I just see you in teaching mode.</p> <p>17 (Laughter.)</p> <p>18 THE COURT: That's okay, it's a tutorial.</p> <p>19 THE WITNESS: I think what I conclude, based on</p> <p>20 having looked at these in great detail, these 31 FULs, and</p> <p>21 having reviewed the testimony and the documents from CMS, is</p> <p>22 that they deviate from this simple rule of 150 percent of</p> <p>23 the lowest published price very, very systematically, in the</p> <p>24 sense that the deviation happens a lot. The manner in which</p> <p>25 they deviate is extremely variable. As I've said, they will</p>	<p style="text-align: right;">33</p> <p>1 THE WITNESS: Well, except that as I view it as an</p> <p>2 economist --</p> <p>3 THE COURT: As a lawyer, they're violating the</p> <p>4 regulation, right? There may be good economic reasons for</p> <p>5 doing it; they're just violating the regulation.</p> <p>6 THE WITNESS: Right, and I'm not a lawyer, your</p> <p>7 Honor. But as an economist, I can see that if you have a</p> <p>8 mandate and one of your objectives is to insure access, that</p> <p>9 would certainly explain why you were going above where your</p> <p>10 regulation tells you to be, because you're certainly not</p> <p>11 doing it to save costs. And if you have two objectives,</p> <p>12 that's the objective that's operational and causes you to go</p> <p>13 above. And the factors that cause you to go above are</p> <p>14 factors that are clearly extraneous to the published</p> <p>15 price -- that's my point -- because you cannot predict from</p> <p>16 the published price how they'd go up in any particular case.</p> <p>17 THE COURT: Is someone here from the federal</p> <p>18 government?</p> <p>19 MR. FAUCI: Jeff Fauci here with the Department of</p> <p>20 Justice, your Honor.</p> <p>21 THE COURT: Good. Don't leave, okay?</p> <p>22 (Laughter.)</p> <p>23 THE COURT: Thank you. Are you involved with the</p> <p>24 AWP case, or they just sent you up here?</p> <p>25 MR. FAUCI: No, I'm with the U.S. Attorney's</p>

<p style="text-align: right;">34</p> <p>1 office upstairs, and I'm involved with working on the cases 2 against Dey and Roxane.</p> <p>3 THE WITNESS: There was just one other chart I 4 wanted to go over quickly, your Honor, which was another 5 FUL, a FUL for Lorazepam 1-milligram pill that was based on 6 prices published in April, 1998, and it was in effect from 7 September, '98, to December, 2000. And the only reason I 8 want to put this up and mention this is that again you have 9 a FUL that was set at .6684.</p> <p>10 MR. BUEKER: This is Slide 18, your Honor.</p> <p>11 THE COURT: Well, the actual FUL that was set was 12 what?</p> <p>13 THE WITNESS: .6684. It's at the very top, your 14 Honor, in the second line of the heading.</p> <p>15 THE COURT: Okay.</p> <p>16 THE WITNESS: And once again there were a variety 17 of lower NDCs, lower-priced NDCs available on which to set 18 the FUL. And this goes to the question you were asking, 19 your Honor. There's a cluster of NDCs here with WACs around 20 2 cents or less, which would have yielded FULs in the range 21 of 2 to 6 cents, just reading down the column of the implied 22 FUL. CMS elects to set a FUL at 66 cents, almost 67 cents.</p> <p>23 And the final striking thing about this is that 24 whatever price CMS used in triggering this FUL -- in other 25 words, whatever price it went and multiplied by</p>	<p style="text-align: right;">36</p> <p>1 it's like a vault from Raiders of The Lost Ark, you know, in 2 a back storage room. So, I mean, if it's not flagged in a 3 brief, we're just not going to get to it.</p> <p>4 BY MR. BUEKER:</p> <p>5 Q. Now, Dr. Addanki, you've shown the Court a couple of 6 examples. Are these in any way unique?</p> <p>7 A. No. I did the same kind of analysis for all 31 FULs, 8 your Honor. And, as I said, the qualitative nature of the 9 departures from picking 150 percent of the lowest published 10 price varied depending on which FUL you're looking at, but 11 in the overwhelming majority of cases, they could have set 12 lower FULs.</p> <p>13 Q. I know you started to do this before, but would you 14 just quickly summarize for the Court your observations, the 15 results of your analysis for all 31 of those FULs.</p> <p>16 A. I'd be happy to, and I'm going to try to get the slides 17 to work as well.</p> <p>18 This is really just what I had said to you 19 earlier, your Honor, that for 23 of the FULs, at the time 20 the FUL was set, there were lower published prices that CMS 21 could have used that it chose not to.</p> <p>22 THE COURT: So it's 23 out of the 31?</p> <p>23 THE WITNESS: At the time the FUL was set, there 24 were already lower published prices available.</p> <p>25 THE COURT: So the other eight were at rock</p>
<p style="text-align: right;">35</p> <p>1 150 percent -- is not among the published prices, and I did 2 a pretty exhaustive search, your Honor.</p> <p>3 So this is a case where CMS set a FUL apparently 4 not using -- even though there were, you know, thirty or 5 forty published prices to choose from, used a price that was 6 not in any of the published prices. And the question that 7 you had asked earlier I think is partially illuminated by 8 this slide about the variation between where they could have 9 gone and where they actually chose to go.</p> <p>10 THE COURT: Okay. And, once again, you don't know 11 the AMPs for any of these, right?</p> <p>12 THE WITNESS: No. I don't believe I have the AMPs 13 for the -- I may have some of them, but I haven't looked at 14 them, your Honor.</p> <p>15 MS. CICALA: They are in the record, if your Honor 16 is interested.</p> <p>17 THE COURT: Do you know that there were so many 18 boxes that were rolled into this office that we actually had 19 to get a separate storage room for them? So I will not be 20 rooting around in the records.</p> <p>21 MS. CICALA: What I mean to say, your Honor, is, I 22 could hand them up to the Court if you'd like to see them.</p> <p>23 THE COURT: That I would love.</p> <p>24 MS. CICALA: Thank you.</p> <p>25 THE COURT: All right. They're actually sitting,</p>	<p style="text-align: right;">37</p> <p>1 bottom?</p> <p>2 THE WITNESS: No, that's not quite it, your Honor.</p> <p>3 For six, it is the case that at the time the FUL was set, 4 the FUL was in fact based on the lowest price available at 5 the time the FUL was set. For two of the other eight, it's 6 not clear what the basis was for the FUL that was chosen; 7 and for 23, there were lower prices available at the time 8 the FUL was set.</p> <p>9 THE COURT: For how many was it the second to 10 lowest? You said at least one lower price. Do you 11 remember?</p> <p>12 THE WITNESS: I haven't got to that.</p> <p>13 THE COURT: Was it a handful?</p> <p>14 THE WITNESS: This typically --</p> <p>15 THE COURT: I mean, you gave me some which are 16 just amazing, but --</p> <p>17 THE WITNESS: Yes, it depends on how many --</p> <p>18 THE COURT: -- do you view this as one tail end of 19 it?</p> <p>20 THE WITNESS: It depends on how many NDCs there 21 are just generally. So if there are only a handful of NDCs 22 at all for the product, then, unsurprisingly, if you're 23 going to get lower ones, you're going to get one or two. 24 But there are drugs for which there are dozens of NDCs with 25 lower prices, and in those cases you have a lot of lower</p>

<p style="text-align: right;">38</p> <p>1 NDCs.</p> <p>2 THE COURT: So do I have this very helpful chart</p> <p>3 for every single one of the 31 NDCs?</p> <p>4 THE WITNESS: You don't have it for literally</p> <p>5 every single one. The presentation has about seven or eight</p> <p>6 of them, your Honor, which we put in there just in case you</p> <p>7 wanted to see them. But there are tables, which I believe I</p> <p>8 have submitted in my declarations and affidavits, that show</p> <p>9 the number of lower NDCs available for each of the FULs in</p> <p>10 effect.</p> <p>11 MR. BUEKER: Your Honor, so you don't have to</p> <p>12 become Raiders of The Lost Ark, why don't we have delivered</p> <p>13 to you a complete set of the arrays.</p> <p>14 THE COURT: That would be useful. Thank you.</p> <p>15 THE WITNESS: And in the second part that I've</p> <p>16 already mentioned to you, your Honor, was that while the FUL</p> <p>17 was in effect, in 29 out of the 31 cases, lower prices were</p> <p>18 published that could have prompted a lower FUL, and CMS</p> <p>19 elected not to do it.</p> <p>20 Q. Now, the Court asked you earlier whether there was</p> <p>21 anything systematic in the way you observed CMS departing.</p> <p>22 Was there?</p> <p>23 A. The answer is "yes" and "no." As I've said, when they</p> <p>24 depart, they only depart in one direction; it's going up.</p> <p>25 But the manner in which they depart, by how much they</p>	<p style="text-align: right;">40</p> <p>1 and you know that they're getting intelligence from outside,</p> <p>2 your first -- well, let me put it this way, your Honor: I</p> <p>3 would expect that if you've got these two objectives, you're</p> <p>4 only going to take the price as high as you feel you need to</p> <p>5 to meet your --</p> <p>6 THE COURT: Suppose everybody on -- I don't know</p> <p>7 if it's true or not, but suppose absolutely everybody on</p> <p>8 this list is lying about the price, and you forced everyone</p> <p>9 to tell the truth, so everyone had to do AMP, and I were to</p> <p>10 go down this list, and everyone would do the AMP.</p> <p>11 THE WITNESS: Right.</p> <p>12 THE COURT: They may well still do this, I don't</p> <p>13 know, fudge-like effort at what it would be, but wouldn't it</p> <p>14 all start at a lower point?</p> <p>15 THE WITNESS: I think, actually, we have the</p> <p>16 perfect natural experiment for that, your Honor.</p> <p>17 THE COURT: Which is?</p> <p>18 THE WITNESS: Which is, when there was a proposal</p> <p>19 to base the FUL on the AMP, you will recall, your Honor,</p> <p>20 that they didn't set it at 150 percent, even for the</p> <p>21 proposal. It was set --</p> <p>22 THE COURT: Who proposed?</p> <p>23 THE WITNESS: CMS proposed -- there was a proposal</p> <p>24 that CMS would set the FULs based on --</p> <p>25 MR. MONTGOMERY: It's actually a Congressional</p>
<p style="text-align: right;">39</p> <p>1 depart, by how many NDCs they depart is entirely variable.</p> <p>2 Q. And you said earlier that you reviewed the CMS</p> <p>3 testimony and documents in this case, correct?</p> <p>4 A. Yes, I did.</p> <p>5 Q. And based on your analysis of the data and your review</p> <p>6 of that testimony and the other evidence that's in the</p> <p>7 record, what conclusions did you reach as an economist about</p> <p>8 how in practice CMS set FULs?</p> <p>9 A. Well, as I said, your Honor, it was clear that rather</p> <p>10 than just rely on this regulation, CMS was relying on market</p> <p>11 intelligence and was exercising its judgment on a</p> <p>12 case-by-case basis to get the FUL to the right level, what</p> <p>13 they thought would be the right level, based on all the</p> <p>14 intelligence they had at their disposal, to balance these</p> <p>15 two cost and access objectives, which are potentially</p> <p>16 conflicting objectives.</p> <p>17 THE COURT: So suppose everybody on this list</p> <p>18 reported something truthfully in terms of what a real</p> <p>19 wholesale acquisition cost is, do you have any basis for</p> <p>20 knowing one way or another what would have happened to the</p> <p>21 price?</p> <p>22 THE WITNESS: I think we have a couple of</p> <p>23 important indicators as to what would have happened to the</p> <p>24 price. I think one important indicator we have is that when</p> <p>25 you see that they are doing this time after time after time,</p>	<p style="text-align: right;">41</p> <p>1 statute, the Deficit Reduction Act of 2005.</p> <p>2 MR. BUEKER: Mandated CMS do this.</p> <p>3 THE COURT: That's when they finally did it.</p> <p>4 MR. BUEKER: Well, no, they didn't do it because</p> <p>5 it was enjoined by a Federal District Court because it</p> <p>6 created access issues.</p> <p>7 THE COURT: That was that one court --</p> <p>8 MR. BUEKER: It's still enjoined. Congress has</p> <p>9 said --</p> <p>10 THE COURT: It's not appealed?</p> <p>11 MR. BUEKER: No. CMS decided not to appeal that,</p> <p>12 your Honor.</p> <p>13 THE WITNESS: Your Honor, the --</p> <p>14 THE COURT: Oh, the guy from Justice, I'm going to</p> <p>15 be asking you questions.</p> <p>16 (Laughter.)</p> <p>17 THE WITNESS: You will recall, your Honor, the</p> <p>18 proposal was for 250 percent of AMP to be used rather than</p> <p>19 150 percent, and --</p> <p>20 THE COURT: It's actually beyond -- I haven't</p> <p>21 spent much time with this because it was post- --</p> <p>22 THE WITNESS: Oh, okay, okay. The proposal was</p> <p>23 that the FUL should be based on 250 percent of the lowest</p> <p>24 AMP, and the OIG and GAO independently conducted studies of</p> <p>25 how --</p>

<p style="text-align: right;">42</p> <p>1 THE COURT: But this is after my time period, 2 right? 3 Q. But, Dr. Addanki, is there anything in your analysis 4 that would suggest that the same kinds of relationships that 5 held after the period wouldn't have held during the period? 6 A. The relationships haven't changed very much, your 7 Honor, between transaction prices and list prices. The 8 basic nature -- 9 THE COURT: Let's say they would have done 10 250 percent of AMP, let's say, where would that have -- and 11 I don't know if we were to do the math -- have you done out 12 the math? Would that have ended up with higher prices? 13 THE WITNESS: At 250 percent of AMP, what the 14 studies found was that for the top 25 Medicaid-reimbursed 15 drugs, 19 out of the 25 drugs would end up with FULs that 16 were below pharmacy acquisition cost. So those FULs 17 couldn't work as a matter of what the FUL was trying to 18 achieve because they were going to be below; the pharmacy 19 was going to be underwater in every prescription. And at 20 150 percent -- I've done the math -- at 150 percent, 24 -- 21 THE COURT: On these 31. 22 THE WITNESS: Okay, the OIG didn't study these 31 23 FULs. 24 THE COURT: All I'm asking is, did you look at 25 these 31? If you were to take AMP and you did, let's say,</p>	<p style="text-align: right;">44</p> <p>1 you looked at. 2 THE WITNESS: They also get information from 3 pharmacies. They get information from manufacturers. They 4 get information from wholesalers, distributors. So they get 5 information essentially from the industry, the marketplace, 6 as to what's going on out there with respect to the 7 different drugs that are covered under Medicaid. So that's 8 the marketplace intelligence that is completely over and 9 above anything in the published prices. 10 Q. Now, Sue Gaston, who we spoke about earlier, provided a 11 declaration in opposition to defendants' motion for summary 12 judgment. Have you looked at that? 13 A. I have. 14 Q. And is what Ms. Gaston says in her declaration 15 consistent with the conclusions that you've reached about 16 how CMS in practice set FULs? 17 A. Yes, it is, your Honor, in the sense that Ms. Gaston 18 does say exactly what I conclude, that she confirms that CMS 19 exercised its discretion, judgment and discretion on a 20 case-by-case basis. 21 She does talk a little bit about, you know, what 22 she might have done in considering NDCs when setting the 23 FULs. She never states it as a rule. She talks about what 24 she might have done, so it doesn't give us much guidance on 25 what they actually did or what they would have done. But I</p>
<p style="text-align: right;">43</p> <p>1 250, or whatever it is you think they might have done, would 2 that have ended up with higher or lower FULs? Did you do 3 that math? 4 THE WITNESS: I think I've already shown you for 5 this Teva case, for instance, you would certainly get a 6 lower FUL if you based it on AMP because the AMP is a lower 7 price. The AMP is a price net of all discounts. It's a 8 manufacturer's net price. The question is, would CMS have 9 set that FUL, given that that FUL would not have covered a 10 pharmacy's acquisition cost for the drug? Right, that's the 11 market intelligence we're talking about as to whether a FUL 12 can actually be set at that level, or if that just wouldn't 13 fly as a matter of what the FUL is supposed to achieve. 14 Q. You've used the term "market intelligence" a couple of 15 times. What do you mean? 16 A. Well, of course, I understand the discussion about 17 AMPs, but CMS has had the AMPs since 1991. They specify how 18 the AMPs should be calculated, and they have them. They 19 have -- 20 THE COURT: But do you know as a matter of 21 practice that people who are setting these prices feel as if 22 they have access to them in order to set the prices? 23 THE WITNESS: I don't know as a matter of what 24 they think. 25 THE COURT: That's fine. That may be beyond what</p>	<p style="text-align: right;">45</p> <p>1 did evaluate whether, if you applied that as a rule, you 2 would then explain, that would be a good model of what CMS 3 actually did in these 31 FULs, and it isn't. 4 THE COURT: So just to refresh my recollection, 5 what exactly did she say she would do? 6 THE WITNESS: She, if I remember right -- well, 7 actually, I think we've got a slide on that, just because I 8 couldn't remember the language. 9 MR. BUEKER: I believe it's Slide 32. 10 THE WITNESS: She says, "If the lowest WAC 11 resulted in a FUL that was higher than at least three 12 published WACs (including the WAC used to calculate the 13 FUL), I would use that WAC to set the FUL. However, if the 14 resulting FUL was not higher than at least three published 15 WACs, I might use the next higher WAC." 16 Q. And did you look at the data and examine whether that 17 rule was in fact followed? 18 A. To the extent that you interpret the "might have" kind 19 of language as a rule, it wasn't followed, your Honor. 20 There are plenty of instances -- I think there were twenty 21 instances where you could lower the FUL and still have a FUL 22 that was higher than at least three published WACs. 23 THE COURT: Now, she's saying this is what you 24 personally would do, or this was what the policy of the 25 agency was?</p>

<p style="text-align: right;">46</p> <p>1 THE WITNESS: I think it's talking about what she</p> <p>2 personally might do.</p> <p>3 MS. CICALA: Your Honor, would you like a complete</p> <p>4 copy of her declaration? I have it here, because we've only</p> <p>5 heard an excerpt that omits obviously --</p> <p>6 THE COURT: I'm sure I have it somewhere. You're</p> <p>7 going to ask about it, right?</p> <p>8 MS. CICALA: Yes. Well, I'm not going to ask</p> <p>9 Dr. Addanki about it because I don't need to ask Dr. Addanki</p> <p>10 what Ms. Gaston said, but I can read what she said.</p> <p>11 THE COURT: I know I've just absolutely hijacked</p> <p>12 this thing.</p> <p>13 MR. BUEKER: No. No, this was meant for your</p> <p>14 benefit.</p> <p>15 THE COURT: How much longer do you have with him?</p> <p>16 MR. BUEKER: Let me just ask a couple of summary</p> <p>17 questions. Then I'll sit down, your Honor.</p> <p>18 Q. Have you reviewed the other summary judgment filings?</p> <p>19 A. Some of them.</p> <p>20 Q. And you're aware of the argument along the line of</p> <p>21 questions the Court was asking about that the plaintiffs</p> <p>22 seem to be advancing that if defendants had reported an</p> <p>23 entirely different lower array of published prices, CMS</p> <p>24 would have set a lower FUL. Did you notice that argument in</p> <p>25 the summary judgment filings you read?</p>	<p style="text-align: right;">48</p> <p>1 tutorial and what happened, right?</p> <p>2 THE WITNESS: I understand, and I guess all I can</p> <p>3 really talk about is what inferences I can draw as an</p> <p>4 economist from what I see, and --</p> <p>5 THE COURT: That's more of an expert witness</p> <p>6 thing, so I think I'm going to stop you there. This has</p> <p>7 been very helpful having you actually go through the data.</p> <p>8 Is there anything else you need to ask? It's not</p> <p>9 like an expert opinion as opposed to a --</p> <p>10 THE WITNESS: No --</p> <p>11 THE COURT: I understand a tutorial is just sort</p> <p>12 of like what happened.</p> <p>13 MR. BUEKER: No, that's fine, your Honor. I mean,</p> <p>14 Ms. Cicala alluded to earlier the fact that this witness has</p> <p>15 done a critique of the plaintiffs' expert, Harris Devor.</p> <p>16 THE COURT: I'm not doing -- this is a tutorial.</p> <p>17 This should just be matter-of-fact literally what happened,</p> <p>18 and that's very helpful. And I understand you've given me</p> <p>19 an expert report for purposes of summary judgment, but I</p> <p>20 think it's starting to bleed into what's somebody's opinion.</p> <p>21 MR. BUEKER: Thank you, your Honor.</p> <p>22 THE COURT: Thank you.</p> <p>23 THE COURT: Although I was probably as guilty of</p> <p>24 it as you were, so, sorry.</p> <p>25 MR. BUEKER: Thank you, your Honor.</p>
<p style="text-align: right;">47</p> <p>1 A. I believe I did, yes.</p> <p>2 Q. And do you as an economist have a reaction to that</p> <p>3 argument, particularly in light of what you've observed CMS</p> <p>4 having done in setting FULs?</p> <p>5 A. I do, and I think I've explained some of it, your</p> <p>6 Honor. I'll just quickly highlight it again. What I</p> <p>7 interpret the plaintiffs to be saying is, had the defendants</p> <p>8 reported transaction prices such as AMPs to the compendia,</p> <p>9 and the compendia published these AMPs in place of the list</p> <p>10 prices that they published, that CMS would have set the FULs</p> <p>11 at 150 percent of these prices, and therefore the FULs would</p> <p>12 have been lower. That's the general understanding I have of</p> <p>13 what the plaintiffs' theory is.</p> <p>14 And what I've shown, I think, is in situations</p> <p>15 where we can see time after time CMS passing over sometimes</p> <p>16 very big NDCs, in terms of sales and availability, that</p> <p>17 could have triggered lower FULs, and CMS was passing over</p> <p>18 those NDCs and electing to set FULs at a higher level, the</p> <p>19 idea that they would have set the FUL at probably a much,</p> <p>20 much lower level just doesn't make economic sense. The</p> <p>21 marketplace factors --</p> <p>22 THE COURT: At this point it's your argument.</p> <p>23 It's not a tutorial in the sense of -- let me just say this:</p> <p>24 Your arguments are very helpful and have some force. It's</p> <p>25 just this is what you're surmising as opposed to just a</p>	<p style="text-align: right;">49</p> <p>1 MS. CICALA: Dr. Addanki can step down.</p> <p>2 THE COURT: Are you done? You don't want --</p> <p>3 MS. CICALA: No, I don't need Dr. Addanki to tell</p> <p>4 me what CMS did, and neither does the Court. So I can talk</p> <p>5 about the CMS testimony --</p> <p>6 THE COURT: Well, what are you going to ask? You</p> <p>7 just ask him questions if you want to.</p> <p>8 MS. CICALA: I have no need to ask Dr. Addanki</p> <p>9 questions at all. Thank you.</p> <p>10 THE COURT: All right, good-bye. Thank you.</p> <p>11 THE WITNESS: Thank you.</p> <p>12 (Witness excused.)</p> <p>13 MS. CICALA: In connection with the tutorial.</p> <p>14 THE COURT: This is all we're talking about is the</p> <p>15 tutorial. Do you want to put your doctor on in terms of the</p> <p>16 tutorial, your expert witness?</p> <p>17 MS. CICALA: Well, I will in a moment. I would</p> <p>18 like, if I may --</p> <p>19 THE COURT: To confer with the team?</p> <p>20 MS. CICALA: No. What I'd like to do is just</p> <p>21 explain to the Court a bit about the evidence that has been</p> <p>22 put into the record. And it's certainly understandable,</p> <p>23 given the volume, that the Court may not --</p> <p>24 THE COURT: I didn't.</p> <p>25 MS. CICALA: Fair enough.</p>

<p style="text-align: right;">50</p> <p>1 THE COURT: In fact, truthfully, I wasn't really a</p> <p>2 hundred percent positive we would be arguing the motions</p> <p>3 today. I wasn't sure if it was going to be consumed with</p> <p>4 the tutorial.</p> <p>5 MS. CICALA: Right. Well, I'm just going to pick</p> <p>6 up -- if I may confine my remarks to the issue of how the</p> <p>7 FUL was set and CMS discretion, there's very little --</p> <p>8 THE COURT: You know what I would prefer to do,</p> <p>9 though?</p> <p>10 MS. CICALA: Certainly.</p> <p>11 THE COURT: I am certainly happy to have you do</p> <p>12 that, but just so I don't hold the witness over, you've now</p> <p>13 rested in terms of your tutorial?</p> <p>14 MR. BUEKER: Yes, your Honor, we have.</p> <p>15 THE COURT: Do you have anybody you want to put on</p> <p>16 for a tutorial? And then I'll let you both -- I think we're</p> <p>17 going to have plenty of time.</p> <p>18 MS. CICALA: In terms of tutorial --</p> <p>19 THE COURT: In other words, what happened. Do you</p> <p>20 disagree -- is he going to refute any of this?</p> <p>21 MS. CICALA: No. Mr. Devor is here to offer</p> <p>22 opinion regarding defendants' actual WACs. He is not here</p> <p>23 to offer an opinion regarding what CMS did. He's just here</p> <p>24 to offer opinion regarding defendants' actual WACs.</p> <p>25 THE COURT: So he's essentially for these 31 NDCs</p>	<p style="text-align: right;">52</p> <p>1 or anything that Ms. --</p> <p>2 THE COURT: You just said you didn't disagree with</p> <p>3 anything Addanki just said.</p> <p>4 MS. CICALA: I said I didn't -- I did not</p> <p>5 disagree -- what I'm trying to --</p> <p>6 THE COURT: Let me just ask you this. He says the</p> <p>7 agency did not follow its own regulation in many instances.</p> <p>8 MS. CICALA: The agency did not apply the, quote,</p> <p>9 "simple rule" in a large number of circumstances.</p> <p>10 THE COURT: Okay, that's point one.</p> <p>11 MS. CICALA: CMS --</p> <p>12 THE COURT: Point two, he says you couldn't figure</p> <p>13 it out, he says, what they would do because they essentially</p> <p>14 did market research and would pick some other number,</p> <p>15 sometimes a real number, sometimes a fictional number.</p> <p>16 MS. CICALA: Disagree.</p> <p>17 THE COURT: You disagree with that?</p> <p>18 MS. CICALA: Yes, and so does CMS. CMS would</p> <p>19 object to that.</p> <p>20 THE COURT: So you disagree with that. And for</p> <p>21 that, you're relying on what Ms. Gaston says, right?</p> <p>22 MS. CICALA: Yes, Ms. Gaston and Ms. Sexton and</p> <p>23 other CMS -- well, those are the two primary CMS witnesses,</p> <p>24 yes.</p> <p>25 THE COURT: So what do you believe was the rule of</p>
<p style="text-align: right;">51</p> <p>1 going to give me the AMP or some equivalent thereto?</p> <p>2 MS. CICALA: He's calculated an alternative WAC,</p> <p>3 and then he has determined what a FUL would have been if any</p> <p>4 of those alternative WACs had been used by CMS. He's a</p> <p>5 forensic accountant.</p> <p>6 THE COURT: According to the literal letter of the</p> <p>7 regulation?</p> <p>8 MS. CICALA: That's correct.</p> <p>9 THE COURT: Not according to the fudgy approach?</p> <p>10 MS. CICALA: Well, we call it the discretion</p> <p>11 approach. Mr. Devor offers no opinion, nor should he --</p> <p>12 THE COURT: How would he know?</p> <p>13 MS. CICALA: -- on what CMS -- Mr. Devor is not</p> <p>14 here to opine on what CMS would have done with defendants'</p> <p>15 actual prices. CMS tells us, through their deposition</p> <p>16 testimony and Ms. Gaston's declaration which is submitted in</p> <p>17 connection with our motion, what CMS --</p> <p>18 THE COURT: Oh, I see. So taking this</p> <p>19 Slide No. 32, he calculates a FUL?</p> <p>20 MS. CICALA: Yes, Mr. Devor has calculated what a</p> <p>21 FUL would look like if it were based on any of defendants'</p> <p>22 actual WACs or based on their AMPs. He did both, your</p> <p>23 Honor.</p> <p>24 MR. BUEKER: To answer your Honor's question</p> <p>25 directly, no, he doesn't do anything with regard to Slide 32</p>	<p style="text-align: right;">53</p> <p>1 thumb according to policy that CMS testified about?</p> <p>2 MS. CICALA: Ms. Gaston tells us what the rule of</p> <p>3 thumb is, and what Ms. Gaston tells us is that she would</p> <p>4 look at the array of prices that was presented to her</p> <p>5 through the FULs printout. We can use the Clonazepam</p> <p>6 example, okay? And, first, she would examine whether the</p> <p>7 lowest price was an outlier; in other words, here it just</p> <p>8 appeared, some whacky number that wasn't in connection with</p> <p>9 the rest.</p> <p>10 THE COURT: No pun intended.</p> <p>11 MS. CICALA: If it was, she would ignore the</p> <p>12 outlier, and then she would look at the next lowest price.</p> <p>13 And this is in her declaration which is consistent with her</p> <p>14 testimony at deposition. She was deposed for more than one</p> <p>15 day.</p> <p>16 If setting the FUL based on the next lowest price</p> <p>17 would result in a FUL that was higher than a few other WACs,</p> <p>18 then she would view that FUL as reasonable and not creating</p> <p>19 access issues, and the FUL would be set at that point. If</p> <p>20 setting the FUL on the next lowest price did not result in a</p> <p>21 FUL that was higher than two WACs, she might move up to the</p> <p>22 next lowest price and the next, and so forth.</p> <p>23 THE COURT: All right. So assume for a minute</p> <p>24 you're roughly accurately describing what she said, is that</p> <p>25 what your expert did?</p>

<p style="text-align: right;">54</p> <p>1 MR. BUEKER: Yes.</p> <p>2 MS. CICALA: What our expert --</p> <p>3 THE COURT: Because that would be useful.</p> <p>4 MS. CICALA: Well, what our expert -- that's a</p> <p>5 damages question, your Honor.</p> <p>6 THE COURT: Well, no, it's also a --</p> <p>7 MS. CICALA: Here's where we morph, if I may</p> <p>8 please finish --</p> <p>9 THE COURT: Yes.</p> <p>10 MS. CICALA: Here's where we morph, I think, from</p> <p>11 tutorial to argument, but here is our fundamental point,</p> <p>12 your Honor, and you were essentially making the same point.</p> <p>13 The array in front of CMS was comprised of false prices in</p> <p>14 an overwhelming majority of cases. Not every single WAC was</p> <p>15 false. Even some of defendants' WACs when we compare them</p> <p>16 to their AMPs were accurate or close to accurate, but</p> <p>17 overwhelmingly they were false, your Honor. And so the</p> <p>18 snapshot that CMS was looking at when it set the FUL did not</p> <p>19 reflect reality. Things that looked like outliers may not</p> <p>20 have in fact been outliers if the truth had been told.</p> <p>21 THE COURT: You're doing great argument. I'm just</p> <p>22 trying to figure out whether I need to hear from your</p> <p>23 expert. What did he do?</p> <p>24 MS. CICALA: He calculated alternative WACs based</p> <p>25 on defendants' actual transaction prices, which is something</p>	<p style="text-align: right;">56</p> <p>1 THE COURT: Do you want to put him on or not</p> <p>2 because I need to -- do you want him? Is he here?</p> <p>3 MS. CICALA: Yes, Mr. Devor is here and can</p> <p>4 explain his methodology to the Court and can address some of</p> <p>5 the criticisms that defendants have leveled against the work</p> <p>6 that he has done.</p> <p>7 THE COURT: Is it a tutorial that will help me</p> <p>8 understand the CMS methodology, which is all I'm doing here</p> <p>9 today?</p> <p>10 MS. CICALA: No. It's more in connection with our</p> <p>11 motion and to demonstrate the falsity of the defendants'</p> <p>12 published prices.</p> <p>13 THE COURT: Fine. I think it's conceded that if I</p> <p>14 say that a WAC has to be some sort of market-based price,</p> <p>15 that it's not going to track AMP in many -- in all 31? Is</p> <p>16 that true? Is that conceded that WAC isn't the same as AMP</p> <p>17 in every single -- I know you're not conceding it's false,</p> <p>18 but --</p> <p>19 MR. MONTGOMERY: That's correct, your Honor.</p> <p>20 AMPs, which of course are filed with CMS, and which, by the</p> <p>21 way, it's important, the testimony from Ms. Gaston is that</p> <p>22 they had access to AMPs. She didn't use them, but she had</p> <p>23 access.</p> <p>24 THE COURT: Well, that's a legal question.</p> <p>25 MR. MONTGOMERY: No, no, as a factual matter, she</p>
<p style="text-align: right;">55</p> <p>1 that defendants --</p> <p>2 THE COURT: And then did what with it?</p> <p>3 MS. CICALA: And then he presents what a FUL would</p> <p>4 have been if based on that alternative WAC.</p> <p>5 THE COURT: But he didn't go through this</p> <p>6 methodology that you say CMS went through?</p> <p>7 MS. CICALA: No, nor should he have as an</p> <p>8 accountant, your Honor. CMS tells us how they would have</p> <p>9 treated accurate prices. And for purposes of liability,</p> <p>10 what we can do and what we have done --</p> <p>11 THE COURT: So I don't need his stuff. Why would</p> <p>12 I need it?</p> <p>13 MS. CICALA: Well, you need it for the context of</p> <p>14 our motion because Mr. Devor's results are among the ways we</p> <p>15 demonstrate the defendants' published WACs were false. So</p> <p>16 he's necessary in connection --</p> <p>17 THE COURT: We know that.</p> <p>18 MS. CICALA: Pardon?</p> <p>19 THE COURT: What's the hard thing to figure out</p> <p>20 is, would it have made a difference?</p> <p>21 MS. CICALA: Well, certainly CMS tells us it</p> <p>22 would, and Ms. Gaston's declaration tells us it would.</p> <p>23 Ms. Gaston's declaration said --</p> <p>24 THE COURT: Do you want to put him on or not?</p> <p>25 MS. CICALA: I can -- well --</p>	<p style="text-align: right;">57</p> <p>1 personally had access. That's the testimony.</p> <p>2 MS. CICALA: Your Honor, your Honor --</p> <p>3 THE COURT: Whoa. Make a decision right now. Do</p> <p>4 you want him on or off the stand?</p> <p>5 MS. CICALA: No.</p> <p>6 THE COURT: Because I'd like to take a break and</p> <p>7 then get into legal argument.</p> <p>8 MS. CICALA: That's fine, your Honor. In</p> <p>9 connection with the tutorial, no, I do not want him on.</p> <p>10 THE COURT: All right, we'll take our break. I'll</p> <p>11 see you at 3:30.</p> <p>12 (A recess was taken, 3:14 p.m.)</p> <p>13 (Resumed, 3:42 p.m.)</p> <p>14 THE COURT: Okay, are you going first?</p> <p>15 MS. CICALA: Yes. Thank you, your Honor.</p> <p>16 The plaintiffs have moved for partial summary</p> <p>17 judgment against the thirteen manufacturers at issue who</p> <p>18 manufactured the non-GCN drugs that we have examined. And</p> <p>19 it's a partial summary judgment motion because we've only</p> <p>20 submitted papers in connection with our claim under New York</p> <p>21 Social Services Law 145-b. New York Social Services</p> <p>22 Law 145-b provides that "It shall be unlawful for a person</p> <p>23 knowingly by means of a false statement to obtain or to</p> <p>24 attempt to obtain payment from public funds." That is the</p> <p>25 violation itself, your Honor, and that is the claim for</p>

<p style="text-align: right;">58</p> <p>1 which we filed our motion.</p> <p>2 The evidence that we have submitted to the Court,</p> <p>3 the record evidence, is that the thirteen defendants</p> <p>4 knowingly submitted, published, false WACs, and in the</p> <p>5 course of doing that, attempted to obtain payment from the</p> <p>6 public fisc, and that activity by itself means that they are</p> <p>7 liable for a violation under 145-b. Relatedly, your Honor,</p> <p>8 our charge here from July --</p> <p>9 THE COURT: Do you have to prove that it caused</p> <p>10 damage?</p> <p>11 MS. CICALA: Well, certainly there's a causal</p> <p>12 nexus between their activity and the result, and that goes</p> <p>13 to Section 2 --</p> <p>14 THE COURT: When you say that, to be clear, you</p> <p>15 agree that you have to prove that it caused injury?</p> <p>16 MS. CICALA: No. I have to prove that their false</p> <p>17 statement was connected to the claim. Let me read</p> <p>18 Section 1(b), okay? "For purposes of this section,</p> <p>19 'statement or representation' includes but is not limited</p> <p>20 to: a claim for payment made to the state, a political</p> <p>21 subdivision of the state, or an entity performing services</p> <p>22 under contract to the state," et cetera, et cetera, or "an</p> <p>23 acknowledgment, certification, claim, ratification or report</p> <p>24 of data --" that's the relevant provision for us -- "which</p> <p>25 serves as a basis for a claim or a rate of payment."</p>	<p style="text-align: right;">60</p> <p>1 submitted evidence of both to your Honor in respect to all</p> <p>2 defendants for all of the drugs at issue.</p> <p>3 THE COURT: What if you can prove that it was</p> <p>4 knowing, and that it was material, and it was a false</p> <p>5 statement, and it had a nexus to the claim, but there's no</p> <p>6 possible way of figuring out --</p> <p>7 MS. CICALA: The damage.</p> <p>8 THE COURT: -- three times the amount by which any</p> <p>9 fee is falsely overstated?</p> <p>10 MS. CICALA: Well, we spent a fair amount of time</p> <p>11 thinking about that because obviously plaintiffs' objective</p> <p>12 on the hearing is to obtain a declaration of liability for</p> <p>13 violation of this provision. Secondly, 145-b has</p> <p>14 essentially a liquidated damages clause, which is our</p> <p>15 starting point for calculating what is the impact --</p> <p>16 THE COURT: But it's not like the federal False</p> <p>17 Claims Act where you get X amount of dollars per false claim</p> <p>18 as an alternative.</p> <p>19 MS. CICALA: No, we don't see that in the statute,</p> <p>20 your Honor. What 145-b-2 provides is that for any</p> <p>21 violation, the district or the state shall have a right to</p> <p>22 recover civil damages equal to three times the amount by</p> <p>23 which any figure is falsely overstated.</p> <p>24 Now, the good news is, for the moment, because we</p> <p>25 have enough on our plates here today, that we don't need to</p>
<p style="text-align: right;">59</p> <p>1 And this is the section that defendants have</p> <p>2 focused on, your Honor. And plaintiffs' position is that</p> <p>3 defendants' submission of false WACs indisputably affected</p> <p>4 where the FUL was set by CMS. The basis of the claim at</p> <p>5 issue here was the FUL, and therefore there's obviously a</p> <p>6 connection between defendants' pollution of the array of</p> <p>7 prices that CMS had in front of it and the FUL that was set.</p> <p>8 So while we do not agree there's a causation in</p> <p>9 terms of damage, in terms of establishing the violation, we</p> <p>10 agree there must be a connection between the false report</p> <p>11 and the basis of the claim. And given that here the basis</p> <p>12 of the claim was the FUL and our position is that the FUL</p> <p>13 was false because of defendants' submission of false prices,</p> <p>14 we believe that we have the causal nexus here.</p> <p>15 It's a slight distinction from the causation</p> <p>16 requirements the defendants are talking about, but certainly</p> <p>17 we acknowledge that there has to be a relationship between</p> <p>18 the false WAC and the basis of the claim, and, again, the</p> <p>19 basis of the claim was the FUL.</p> <p>20 What plaintiffs have submitted by way of record</p> <p>21 evidence to demonstrate the falsity of defendants' WACs are</p> <p>22 an assortment -- we have an assortment of materials. First</p> <p>23 of all, we have alternative WACs calculated by Mr. Devor</p> <p>24 which demonstrate that the published WACs of defendants were</p> <p>25 false, and we also have the defendants' AMPs. And we have</p>	<p style="text-align: right;">61</p> <p>1 answer the question of how we're going to resolve damages</p> <p>2 before agreeing that we have established a violation on the</p> <p>3 basis of the submission of the false prices. And if I may,</p> <p>4 I want to revisit a little bit about the impact of the</p> <p>5 false --</p> <p>6 THE COURT: What if there's no possible way of</p> <p>7 figuring out damages?</p> <p>8 MS. CICALA: Well, there is in fact, your Honor,</p> <p>9 and in general the way to do it would be to look at what FUL</p> <p>10 was set in the false world based on the false array that had</p> <p>11 been created versus what the FUL would have been if</p> <p>12 defendants had reported accurate prices, and that is the</p> <p>13 starting point for an evaluation of damages.</p> <p>14 Now, the question then becomes, how do you measure</p> <p>15 each individual defendants' damages in connection with their</p> <p>16 prices? And the answer to that is admittedly somewhat</p> <p>17 complicated, but it is doable. And certainly the fact that</p> <p>18 it's complicated, at least under New York law, doesn't mean</p> <p>19 that we don't give it a try or that we find that they're not</p> <p>20 liable for the violation in the first place. There's</p> <p>21 questions of whether the defendants should be held joint and</p> <p>22 severally liable for the damage. That's something to be</p> <p>23 explored. There's also perhaps --</p> <p>24 THE COURT: Have you sued everybody who had a</p> <p>25 therapeutic equivalent with a false WAC?</p>

<p style="text-align: right;">62</p> <p>1 MS. CICALA: All that's at issue on this motion, 2 your Honor, are thirteen defendants and their pricing 3 practices. We have not sued everybody. And as we go 4 through the record evidence, the fact is that there are 5 certainly occasions where the defendants, the true WAC or 6 the actual WAC and their AMP are close to what they 7 reported. And in such events, there may be good reason -- 8 well, there's no liability in that case.</p> <p>9 But the interesting question for us, or among them 10 with respect to damages, what do we do with the defendants 11 whose prices were ignored? Because CMS did, Ms. Gaston did 12 indisputably, because of her access concerns, overlooked 13 sort of the low-flying WACs; and when presented with the 14 true array, she may well have done the same. And plaintiffs 15 certainly would be prepared to sort of live and die by what 16 Ms. Gaston did before and what it would have done in a 17 truthful world. And perhaps the --</p> <p>18 THE COURT: Why is she so critical? Who was she? 19 MS. CICALA: She set the FULs from -- 20 THE COURT: Who was she? 21 MS. CICALA: -- the early '80s until -- hang on. 22 She set the FULs for a twelve-year period, so for the 23 majority of time at issue in our case, Ms. Gaston set the 24 FULs. 25 THE COURT: Is she a high-level person or a</p>	<p style="text-align: right;">64</p> <p>1 reasons. The issue is that the world in which CMS was 2 operating at the outset was not an accurate world. And as 3 your Honor was alluding to earlier, and if I may just pick 4 up on this thread, the arrays of prices that CMS would have 5 been looking at would have been an entirely different array 6 had defendants reported accurate prices. And Ms. Gaston in 7 fact I think provides the information that your Honor was 8 alluding to earlier as well. She says, "If alternative 9 prices had been presented, I would have considered them, and 10 the FUL likely would have been lower." And in her 11 declaration, Ms. Gaston, if I may hand up a copy, in her 12 declaration, Ms. Gaston specifically addresses two drugs at 13 two points in time when CMS did set -- may I approach?</p> <p>14 THE COURT: Yes. 15 MS. CICALA: -- when CMS did set the FUL, 16 Metoprolol and also cefadroxil. And what Ms. Gaston says 17 is -- plaintiffs provided Ms. Gaston with an alternative 18 array of prices that was populated by the alternative WACs 19 calculated by Mr. Devor and then a different array populated 20 with the defendants' AMPs, and asked Ms. Gaston, "Had you 21 been presented with these arrays, what would you have done?" 22 And in her declaration, Ms. Gaston describes what she would 23 have done. And in both occasions, it's no surprise the FUL 24 would have been lower than what it was. And in both 25 occasions, a simple rule would not have been applied, but</p>
<p style="text-align: right;">63</p> <p>1 low-level person?</p> <p>2 MS. CICALA: Well, she was responsible for setting 3 the FULs, and she was deposed -- she set the FULs from April 4 of '91 to February of 2003, and she was deposed by 5 defendants. The other two individuals who set the FULs were 6 Cindy Bergen and Gail Sexton. Ms. Sexton also was deposed, 7 and excerpts from their deposition testimony is in the 8 record and explains their methodology, which was generally 9 consistent. And Dr. Addanki accurately described that there 10 were departures from the strict adherence to the simple rule 11 where they took the lowest published price and marked it up 12 150 percent.</p> <p>13 THE COURT: Because the rule as worded on its face 14 was violated, and so they basically tried to do justice 15 basically.</p> <p>16 MS. CICALA: Well, I mean, if you look at the 17 inception of the FUL program, if you look at why the FUL -- 18 THE COURT: I understand that. The rule says what 19 it says. 20 MS. CICALA: Yes, and, listen, we're -- 21 THE COURT: And it looks as if the plain language 22 of the rule was violated, maybe for good reason, but it was 23 violated. 24 MS. CICALA: Yes, I think the parties agree that 25 CMS exercised discretion, and it did so for sound policy</p>	<p style="text-align: right;">65</p> <p>1 nevertheless the FUL would have been lower.</p> <p>2 It simply defies common sense that in a real world 3 with accurate prices, the FUL would have remained where it 4 was, and that's all that plaintiffs need to establish for 5 the violation of 145-b. When we get into the damages 6 questions, your Honor, the question would be to go through 7 NDC by NDC and evaluate what the FUL would have been had the 8 accurate prices been reported.</p> <p>9 THE COURT: Under this methodology she outlined? 10 MS. CICALA: Yes. 11 THE COURT: And that's what your expert has not 12 done? 13 MS. CICALA: No. That's not what we're here on 14 today. We're here to demonstrate -- I mean, the genesis of 15 the hearing today was, your Honor was reluctant to permit, 16 you know, widespread discovery on all of the -- sorry.</p> <p>17 THE COURT: I've got your argument, and it's 18 pretty straightforward. Can I ask you about government 19 knowledge for a minute? 20 MS. CICALA: Certainly. 21 THE COURT: So this is highly different from my 22 other cases because in the other cases, as you know, it's 23 published in a book, and by statute the government had to 24 follow it, and there was no price-setting. Here CMS set the 25 price, and CMS has the AMP.</p>

<p style="text-align: right;">66</p> <p>1 MS. CICALA: Ms. Gaston --</p> <p>2 THE COURT: So they have it. And it's very</p> <p>3 different from all my other cases. It's a much closer</p> <p>4 government-knowledge case. So I'd like -- did she say she</p> <p>5 looked at them?</p> <p>6 MS. CICALA: No, and I'll tell you, first of</p> <p>7 all --</p> <p>8 THE COURT: Did she say she had access to them?</p> <p>9 MS. CICALA: Yes. She says in fact CMS received</p> <p>10 the AMPs, but what she says --</p> <p>11 THE COURT: But would she have gone and received</p> <p>12 the AMPs to actually check for accuracy?</p> <p>13 MS. CICALA: She testified that she did not do</p> <p>14 that because they were not published prices, and so she</p> <p>15 could not use them, and she understood they could not be</p> <p>16 used for reimbursement.</p> <p>17 THE COURT: So is that in this affidavit?</p> <p>18 MS. CICALA: Yes, it is in the affidavit at</p> <p>19 Paragraph 6: "Although CMS received average manufacturer</p> <p>20 prices (AMPs) from manufacturers for the sole purpose of use</p> <p>21 in the Medicaid drug rebate program, I understood that AMPs</p> <p>22 were confidential, could not be used for reimbursement</p> <p>23 purposes, and, in any event, AMPs were not prices published</p> <p>24 in the national compendia and by law could not be used for</p> <p>25 setting FULs. Therefore, I did not consider AMPs to set</p>	<p style="text-align: right;">68</p> <p>1 scenario here where the law is going to take us on a limb</p> <p>2 that doesn't make any practical sense. Think of the</p> <p>3 implications of the defendants' or AMP argument, that every</p> <p>4 civil servant, including Ms. Gaston, would be charged when</p> <p>5 being presented -- or any civil servant when being presented</p> <p>6 with a claim is charged with determining the veracity of</p> <p>7 that claim. The government could not function that way.</p> <p>8 The onus is on the entity who's --</p> <p>9 THE COURT: I'm just trying to understand. Just</p> <p>10 back up for one minute. Is there a government-knowledge</p> <p>11 defense under state law?</p> <p>12 MS. CICALA: No, not to 145-b. There's no --</p> <p>13 THE COURT: How do we know that?</p> <p>14 MS. CICALA: From the plain language of the</p> <p>15 statute. And there are no cases, there are no cases stating</p> <p>16 that there is a government-knowledge defense.</p> <p>17 THE COURT: Are there cases that say that they</p> <p>18 follow the False Claims Act on the federal government claims?</p> <p>19 MS. CICALA: Absolutely, and we've distinguished,</p> <p>20 we've talked about them in our briefs, your Honor. And</p> <p>21 certainly where you have a situation where there is an</p> <p>22 agreement between the government and the person submitting</p> <p>23 the claim, there's some sort of express agreement, in this</p> <p>24 case it would look something like this: "Yes, we know your</p> <p>25 WACs are false. Yes, we know how much they're false, and</p>
<p style="text-align: right;">67</p> <p>1 FULs."</p> <p>2 THE COURT: And would that have been true</p> <p>3 throughout the period of time we're talking about?</p> <p>4 MS. CICALA: Yes, your Honor. Yes, your Honor.</p> <p>5 THE COURT: So the narrow legal question is,</p> <p>6 unlike all my other cases, here the agency has the AMPs, has</p> <p>7 full access to the AMPs, and the question is whether or not</p> <p>8 that triggers the government-knowledge defense.</p> <p>9 MS. CICALA: Well, you know, 145-b would say "no,"</p> <p>10 your Honor, which makes --</p> <p>11 THE COURT: Let me just make it clear. If she</p> <p>12 herself had them sitting side by side as I asked him to do,</p> <p>13 I would say that the government-knowledge defense was</p> <p>14 triggered, okay, because if ever it were triggered, if she</p> <p>15 actually had them and knew. What's the harder question is</p> <p>16 where one part of the agency has it and the other part</p> <p>17 doesn't, whether or not the knowledge of one program is</p> <p>18 attributable to another. It's a harder question than I've</p> <p>19 had in any of my other cases. It's much closer.</p> <p>20 MS. CICALA: I understand. If I may be heard on</p> <p>21 that just for a moment.</p> <p>22 THE COURT: Is there a case on point?</p> <p>23 MS. CICALA: Well, there -- 145-b shares many of</p> <p>24 the attributes with standard False Claims Act cases. And,</p> <p>25 you know, what's interesting here is, we don't have a</p>	<p style="text-align: right;">69</p> <p>1 we're going to use them anyway," which is essentially what</p> <p>2 defendants' argument is, right?</p> <p>3 THE COURT: Well, skip the agreement. Suppose</p> <p>4 everything you just said, we know they're false, and then</p> <p>5 they continue to use it.</p> <p>6 MS. CICALA: We know they're false, we know how</p> <p>7 much they're --</p> <p>8 THE COURT: Subjectively, this woman Gaston</p> <p>9 actually -- suppose you had that situation -- actually knew</p> <p>10 they were false and then continued to use.</p> <p>11 MS. CICALA: Look, if the government -- if the</p> <p>12 government -- the government obviously can choose to conduct</p> <p>13 itself on the basis of false data if it wants. The question</p> <p>14 is, is it informed that the data is false? And Ms. Gaston,</p> <p>15 there is no testimony that Ms. Gaston knew the WACs were</p> <p>16 false. In fact, if you look at the record evidence put in</p> <p>17 from the defendants in this case, your Honor, they took</p> <p>18 twenty CMS depositions, twenty different witnesses over</p> <p>19 twenty-eight days, and they don't have a stitch of evidence</p> <p>20 that those witnesses believed the WACs to be false, not a</p> <p>21 stitch of evidence from twenty witnesses. CMS, just like</p> <p>22 the state Medicaid programs, your Honor, believed the WACs</p> <p>23 were accurate, and that EAC lay somewhere between WAC and</p> <p>24 AWP. That was the belief. As the years progressed and</p> <p>25 knowledge came to the fore about the falsity of the WAC, you</p>

<p style="text-align: right;">70</p> <p>1 see the reaction. You see CMS now endeavoring, or through</p> <p>2 Congress, to put in place different ways to set the FUL</p> <p>3 because the knowledge has developed, and now they know the</p> <p>4 WACs are in fact not true.</p> <p>5 THE COURT: At what point is that?</p> <p>6 MS. CICALA: It's consistent with your findings in</p> <p>7 Mylan, your Honor. You've got the Medicare Modernization</p> <p>8 Act in 2003 that for the first time defines WAC as a list</p> <p>9 price, okay. That's another fact indisputable, right? That</p> <p>10 definition had not been previously codified. There was</p> <p>11 not --</p> <p>12 THE COURT: So might there be a different analysis</p> <p>13 between 2003 and 2005?</p> <p>14 MS. CICALA: Yes, there very well might. There</p> <p>15 very well might. But what there is not is any record</p> <p>16 evidence that the government understood WACs to be false</p> <p>17 prior to that point. There simply is not, and, again, nor</p> <p>18 have defendants put it in front of your Honor. And you can</p> <p>19 look at how CMS was conducting itself in respect of the FUL-</p> <p>20 setting process to demonstrate that. You can look at the</p> <p>21 state Medicaid programs, the multi-state chart. I don't</p> <p>22 know if your Honor has seen the CMS multi-state chart.</p> <p>23 Every single state in the country is either WAC plus or AWP</p> <p>24 minus because everyone thinks the truth is somewhere in</p> <p>25 between.</p>	<p style="text-align: right;">72</p> <p>1 excellent one, which is, all right, you have CMS, for a</p> <p>2 period of time for sure they believed WACs were truthful.</p> <p>3 That's why they moved off of AWP to WAC, but at some point</p> <p>4 it became clear that WACs weren't even good. So there's</p> <p>5 going to be a period of time where government knowledge, you</p> <p>6 don't have to go around ferreting, but at some point there's</p> <p>7 some sort of inquiry knowledge, they know, so why aren't</p> <p>8 they then going in and checking?</p> <p>9 MS. CICALA: Well, if you study the testimony of</p> <p>10 the CMS witnesses, you see, as the years go by, there is</p> <p>11 more of an application of the simple rule as there is this</p> <p>12 recognition that what they're looking at may not actually</p> <p>13 reflect reality. So in the context of doing a damages</p> <p>14 analysis here, if we calculated damages based on what CMS</p> <p>15 did in the old world and then we take those same choices,</p> <p>16 even if they ignored some of the low WACs, and we import</p> <p>17 that into the true world, then we'll see as over time</p> <p>18 there's more of a selection of the lowest WAC.</p> <p>19 THE COURT: Just help me through. What's the</p> <p>20 period of time where you would say there's absolutely no</p> <p>21 knowledge that anyone in the agency even had inquiry notice</p> <p>22 to look at AMPs?</p> <p>23 MS. CICALA: Certainly through the end of 2002,</p> <p>24 your Honor.</p> <p>25 THE COURT: All right, so you would say through</p>
<p style="text-align: right;">71</p> <p>1 THE COURT: No, they don't. It's unbelievable</p> <p>2 that there are still states in the United States of America</p> <p>3 operating off of AWP, and if they want to eat that money,</p> <p>4 they can eat it. I mean, it's extraordinary to me. So, I</p> <p>5 mean, at some point they've got to have some responsibility,</p> <p>6 but the question is what point that is.</p> <p>7 MS. CICALA: I agree, I agree. I completely</p> <p>8 agree. There's no disputing that, your Honor. But the</p> <p>9 question is, what is that point, and what does the evidence</p> <p>10 show the knowledge to be? And defendants here, after all</p> <p>11 this testimony from CMS, they can't show knowledge of</p> <p>12 falsity of WAC. And instead they've submitted evidence to</p> <p>13 the Court --</p> <p>14 THE COURT: Well, at some point before 2003, they</p> <p>15 must have known because the bill passed then, so they must</p> <p>16 have been submitting things to Congress. At what point did</p> <p>17 they --</p> <p>18 MS. CICALA: Well, you know, in your Mylan</p> <p>19 decision, you start talking about murmurings of this in late</p> <p>20 2001 and 2002, and then you say certainly by '03. And the</p> <p>21 defendants have submitted some different evidence knowledge</p> <p>22 here, your honor, but it's of the same ilk. None of it</p> <p>23 demonstrates actual knowledge of the government that these</p> <p>24 WACs are completely decoupled from reality, which is --</p> <p>25 THE COURT: Let's take your argument, which is an</p>	<p style="text-align: right;">73</p> <p>1 2002?</p> <p>2 MS. CICALA: Yes, yes.</p> <p>3 THE COURT: And then after that, there might be a</p> <p>4 disputed issue of fact, you would say. I'm just trying to</p> <p>5 understand.</p> <p>6 MS. CICALA: You know, because what we have, in</p> <p>7 2004 the OIG does its first real report on how the FUL is</p> <p>8 working.</p> <p>9 THE COURT: In 2003 we have the statute, so --</p> <p>10 MS. CICALA: Right, that's right, we do. We do.</p> <p>11 THE COURT: So, all right, I'll think about that</p> <p>12 one. Thank you.</p> <p>13 MS. CICALA: And can I make one other small point</p> <p>14 on this array issue, your Honor?</p> <p>15 THE COURT: Yes.</p> <p>16 MS. CICALA: Absolutely true that the lower prices</p> <p>17 were ignored. There's no dispute on these facts, your</p> <p>18 Honor. But if you look at what Ms. Gaston -- if you look at</p> <p>19 what was done here, the array of prices range from 7 cents</p> <p>20 to 84 cents, and the WAC that was chosen was 16 cents. And</p> <p>21 if you look through the printouts that we have submitted in</p> <p>22 connection with our papers and if you look at the excerpts</p> <p>23 of the deposition testimony, you'll see that whatever was</p> <p>24 selected was always towards the low end of the array,</p> <p>25 always. So it simply defies logic, and it also would be</p>

<p style="text-align: right;">74</p> <p>1 contrary to the CMS testimony, including the declaration, to 2 believe that if the prices represented in this array shifted 3 downward in the main, the FUL would remain the same or be 4 higher somehow. It's completely contrary to logic or the 5 CMS witnesses' testimony. And so that is why we feel quite 6 certain with our position, your Honor, that defendants' 7 false prices create a fictional universe that CMS had to 8 operate in, and the FUL was indisputably higher as a result. 9 And that, frankly, is all we need under 145-b for liability.</p> <p>10 Damages is another day, and we look forward to 11 that hearing, and we look forward to expert reports to deal 12 with it because it can be addressed. But on the liability 13 issue, your Honor, it's simply indisputable that by creating 14 this fictional array, the FUL was higher than it otherwise 15 would have been.</p> <p>16 THE COURT: Okay, thank you.</p> <p>17 MR. MONTGOMERY: Your Honor, let me go back to 18 where I think your Honor started earlier in the tutorial, 19 back to July 30 of 2007 when you actually issued the order 20 that led to this very hearing. And in that order, you 21 denied the defendants' renewed motion to dismiss, a motion 22 to dismiss which was based upon a public record in which we 23 told you CMS didn't comply with the FUL regulation. But 24 nevertheless you issued an order saying, well, we were going 25 to have a narrow, focused hearing on a test set of drugs</p>	<p style="text-align: right;">76</p> <p>1 would have been glad to depose policy-makers, but we were 2 not given that choice. We were given Sue Gaston, who you've 3 suggested may be a relatively low-level employee.</p> <p>4 THE COURT: Well, I have no idea who she is.</p> <p>5 MR. MONTGOMERY: Well, she is the person in 6 charge, but she's clearly not a policy-maker. But she is 7 applying policy-based judgments, and she's doing it each and 8 every time they set a WAC. And as Dr. Addanki told you, in 9 most every instance, not every but in most every instance, 10 they ignore the rule. In every single instance, she makes a 11 policy judgment. Even if she picks, as she did twice, the 12 lowest published WAC, she makes a policy judgment that 13 that's an appropriate level at which the federal government 14 should establish the upper limit of reimbursement. And she 15 does that in every single instance on the basis --</p> <p>16 THE COURT: If you take her description of what 17 she did, though, it wasn't like throwing a dart.</p> <p>18 MR. MONTGOMERY: No.</p> <p>19 THE COURT: She moves up from the bottom. So if 20 the bottom were much lower, isn't it fair to infer that the 21 ultimate price she would have set in the lower universe 22 would have been lower?</p> <p>23 MR. MONTGOMERY: No -- well, let's step aside from 24 Sue Gaston. I don't know what Sue Gaston would have done. 25 It is clear that's not what CMS would have done because we</p>
<p style="text-align: right;">75</p> <p>1 that would be agreed upon by plaintiffs and defendants. And 2 you said that "The plaintiffs have to allege and prove that 3 the defendants submitted false or inflated published prices, 4 which, if truthful, would likely have affected the FUL." 5 That's what we're doing here today because as Ms. Cicala 6 concedes, there is a causation requirement. She can parse 7 that language any way she wishes, but the fact is that for a 8 statement to be false, it has to be the basis of the FUL. 9 So you got it right.</p> <p>10 THE COURT: But the tough point for me is, if 11 everybody in that list had reported a truthful WAC, isn't it 12 likely that the FUL would have been lower?</p> <p>13 MR. MONTGOMERY: Absolutely not.</p> <p>14 THE COURT: That's where I'm not sure. I'm not 15 sure you can figure out how much lower, but why not?</p> <p>16 MR. MONTGOMERY: Well, I think several reasons. 17 First of all, we have an agency that, notwithstanding what 18 they published in the federal record, is applying a policy 19 judgment. We have done the most complete inquiry that we 20 have been able to accomplish in two years regarding that 21 policy-based system. It's a shadow system, your Honor, that 22 CMS was operating.</p> <p>23 Contrary to what Ms. Cicala just told you about 24 our depositions of twenty CMS witnesses, that never 25 happened. We were allowed to depose two CMS witnesses. We</p>	<p style="text-align: right;">77</p> <p>1 know that CMS has had quarterly AMPs from each of the 2 defendants since 1991. The period here starts in 1996.</p> <p>3 THE COURT: But suppose you have an agency which 4 unfortunately operates out of silos.</p> <p>5 MR. MONTGOMERY: Well, your Honor, there is --</p> <p>6 THE COURT: No, no, just this is the narrow legal 7 question. This is the first time the government-knowledge 8 defense, in my view, has been fairly teed up, actually, 9 because here we actually have one agency that has both sets 10 of information, but one program is not talking to the other 11 program, so this is a much closer call than any of the other 12 cases I've had.</p> <p>13 MR. MONTGOMERY: To that point, your Honor, we 14 have no evidence, you have no evidence that there are silos 15 here.</p> <p>16 THE COURT: I have no evidence that anyone 17 actually talked.</p> <p>18 MR. MONTGOMERY: Let me show you a piece of 19 evidence and put up on the screen a slide.</p> <p>20 THE COURT: Do I have it?</p> <p>21 MR. MONTGOMERY: Actually you don't have it. 22 Well, you do have it. It is Exhibit B to the defendants' 23 reply brief in support of our motion for summary judgment. 24 So what we have, and I concede that it's not a robust 25 record, but this is an agency that is trying to deny us</p>

<p style="text-align: right;">78</p> <p>1 access to information, your Honor. We have Sue Gaston</p> <p>2 saying, "Yes, I had access to the AMPs," not that it was</p> <p>3 siloed. That's her deposition testimony.</p> <p>4 THE COURT: What does this mean, "Could you try</p> <p>5 MDR again"?</p> <p>6 MR. MONTGOMERY: Right, now, let me -- so we have</p> <p>7 Sue Gaston's testimony. Now we have an e-mail, and an</p> <p>8 e-mail from somebody we understand to be Sue Gaston's</p> <p>9 superior named Larry Reed. And in connection with a drug</p> <p>10 that I know your Honor is familiar with from another</p> <p>11 context, Neurontin, several days prior to this e-mail --</p> <p>12 THE COURT: Is this on-label or off-label?</p> <p>13 MR. MONTGOMERY: -- several days prior to this</p> <p>14 e-mail, the OIG issued a report regarding CMS's</p> <p>15 administration of the FUL system. They mentioned the drug</p> <p>16 Neurontin. This exchange concerns Neurontin. What Gail</p> <p>17 Sexton, Sue Gaston's colleague, says is, "Well, gee, I'm not</p> <p>18 sure we can set a FUL on Neurontin because there's a lack of</p> <p>19 current information in the system." And Larry Reed says,</p> <p>20 "Check again in the MDR." That's their AMP computer system.</p> <p>21 "Are AMPs available?" He's essentially saying, can we use</p> <p>22 AMPs?</p> <p>23 THE COURT: So this is in January of 2005?</p> <p>24 MR. MONTGOMERY: That's right. But, your Honor,</p> <p>25 I'm not -- and I'm not trying to make a point that the</p>	<p style="text-align: right;">80</p> <p>1 MR. MONTGOMERY: That's right.</p> <p>2 THE COURT: But they didn't, and they didn't</p> <p>3 actually know what they were.</p> <p>4 MR. MONTGOMERY: No. What you have is that the</p> <p>5 individual setting the FULs --</p> <p>6 THE COURT: Fair enough.</p> <p>7 MR. MONTGOMERY: -- did not access the AMPs, at</p> <p>8 least the individual who's testified. Gail Sexton may well</p> <p>9 have accessed the AMPs. Certainly Larry Reed is treating in</p> <p>10 this 2005 instruction access to AMPs by these line employees</p> <p>11 as a relatively routine matter.</p> <p>12 But as a record point, your Honor, this is summary</p> <p>13 judgment. We plainly have shifted the burden, in Celotex</p> <p>14 terms, to the plaintiffs. They have the obligation under</p> <p>15 your order to show that it's likely that CMS, if they had</p> <p>16 had WACs published as AMPs, that it would have made a</p> <p>17 difference. They can't show that, both because CMS always</p> <p>18 had access to AMPs, and because when CMS actually looked at</p> <p>19 Congressional direction at changing to an AMP-based system,</p> <p>20 they couldn't do it. It's still being studied. And we can</p> <p>21 give you all the chapter and verse you'd like on the</p> <p>22 question, but just recently, in the last month, the judge in</p> <p>23 the AMP/FUL case has amended his preliminary injunction to</p> <p>24 permit AMPs to be disclosed to GAO so that they can conduct</p> <p>25 a study to see whether 300 percent of AMP might work. So</p>
<p style="text-align: right;">79</p> <p>1 timing is -- it's just that this is a clear administrative</p> <p>2 communication within this agency that has made it very, very</p> <p>3 difficult for the defendants to actually explain the truth</p> <p>4 to this Court, the truth that we told you was plain on the</p> <p>5 record.</p> <p>6 THE COURT: I've got to go on the record that I've</p> <p>7 got, which is --</p> <p>8 MR. MONTGOMERY: That's right.</p> <p>9 THE COURT: -- I think it would be fair to assume</p> <p>10 that, based on what I've got, that the people who were</p> <p>11 setting the FULs were not actually accessing the AMPs, but</p> <p>12 they had access to them if they wanted to.</p> <p>13 MR. MONTGOMERY: Exactly.</p> <p>14 THE COURT: I think they felt they couldn't look</p> <p>15 at them because they weren't published prices, but they</p> <p>16 could have gotten access if they wanted to. The question</p> <p>17 is, is that enough to trigger a government-knowledge</p> <p>18 defense?</p> <p>19 MR. MONTGOMERY: And, your Honor, they could have</p> <p>20 changed the FUL system at any time they wished to an</p> <p>21 AMP-based system. If you look at the so-called --</p> <p>22 THE COURT: I understand all that, but as I</p> <p>23 understand it, the only record I have is, they could have</p> <p>24 gotten -- they could have received access to the AMPs if</p> <p>25 they wanted to.</p>	<p style="text-align: right;">81</p> <p>1 that when CMS tried this, they couldn't do it. So that's</p> <p>2 all the evidence you need that in the real world, that a</p> <p>3 full array of AMP-based prices, not just the defendants' but</p> <p>4 everyone, could not have worked at 150 percent of AMP.</p> <p>5 THE COURT: Is it a federal judge, I assume?</p> <p>6 MR. MONTGOMERY: Yes.</p> <p>7 THE COURT: Who?</p> <p>8 MR. MONTGOMERY: Royce Lambert. And, you know,</p> <p>9 it's been a well-litigated and hotly litigated case in which</p> <p>10 we take note of the fact that the Department of Justice</p> <p>11 decided not to take an appeal from that preliminary</p> <p>12 injunction, in the face of reports from the GAO and the OIG</p> <p>13 that this wouldn't work.</p> <p>14 THE COURT: So suppose you had 300 percent of AMP,</p> <p>15 would that still be lower than what --</p> <p>16 MR. MONTGOMERY: You know, your Honor, would it be</p> <p>17 lower? Yes, it would probably be lower than some of these,</p> <p>18 but, again, that's a matter that's still the subject of</p> <p>19 study. What the burden here is for the plaintiffs, because,</p> <p>20 as I said, we have shifted it to them, they've got to show</p> <p>21 that it's likely that in these instances between 1996 and</p> <p>22 2005, that the agency actually would have taken the</p> <p>23 published prices and would have published AMPs that we now</p> <p>24 know, on the basis of published reports, could not have</p> <p>25 worked. And as Dr. Addanki told you, you know, during the</p>

<p style="text-align: right;">82</p> <p>1 period 2005 to 2008, there's no substantial difference in</p> <p>2 the economics of pricing in the pharmaceutical industry.</p> <p>3 THE COURT: Part of the issue is that the whole</p> <p>4 system is perfused with problematic pricing. If truthful</p> <p>5 WACs had been published in the Blue Books, then is it likely</p> <p>6 that the pharmacies would have been paying less? So, in</p> <p>7 other words, we wouldn't have a crisis, or at least there</p> <p>8 would be a crisis at a lower level of magnitude.</p> <p>9 MR. MONTGOMERY: Your Honor, I think that's</p> <p>10 entirely speculative. I don't think there's any evidence</p> <p>11 that the availability of AMPs in the post-perfect storm era,</p> <p>12 availability of ASPs, has made any difference to what</p> <p>13 pharmacies are actually paying. So I think I understand</p> <p>14 your question, it's a legitimate question, but it's --</p> <p>15 THE COURT: I have no idea.</p> <p>16 MR. MONTGOMERY: -- just not part of this record.</p> <p>17 And if the dramatic falloff that might be implied by</p> <p>18 plaintiffs' arguments all these years had occurred, I think</p> <p>19 that we would all know about it because it would be a big</p> <p>20 item of discussion nationally. It just hasn't occurred.</p> <p>21 THE COURT: All right, well, you don't know</p> <p>22 either, so --</p> <p>23 MR. MONTGOMERY: I don't know.</p> <p>24 THE COURT: It's not part of this record.</p> <p>25 MR. MONTGOMERY: It's not part of this record.</p>	<p style="text-align: right;">84</p> <p>1 Now, we don't think it is inconsistent.</p> <p>2 THE COURT: Do I have her full deposition?</p> <p>3 MR. MONTGOMERY: Yes. We have submitted -- I have</p> <p>4 it here, but we have also submitted as one of our summary</p> <p>5 judgment exhibits in one of those boxes a copy of it. I can</p> <p>6 certainly hand this one up to your Honor.</p> <p>7 THE COURT: I actually would like that. It flags</p> <p>8 for me one of the problems in this case. I suppose you all</p> <p>9 feel like you need to paper it to death for an appeal,</p> <p>10 should one come, but it makes it unrealistic for me to even</p> <p>11 keep the materials in my office. I'm sure you have an</p> <p>12 office designated at your firms for this.</p> <p>13 MR. MONTGOMERY: Yes.</p> <p>14 THE COURT: And I'm wondering whether there's a</p> <p>15 way in the future to just flag, like you do at a hearing,</p> <p>16 which is lovely, just a few key things that I really sort of</p> <p>17 must read kind of thing, and the rest is just for my bedtime</p> <p>18 pleasure, you know. But it's useful to bring up just a</p> <p>19 couple of the key things, and I appreciate them at the</p> <p>20 hearings, and they're the kind of things I will sit down and</p> <p>21 read myself.</p> <p>22 MR. MONTGOMERY: One more thing that I do want to</p> <p>23 point out to your Honor about Ms. Gaston because I think the</p> <p>24 plaintiffs have said here today, and I think you'll find</p> <p>25 when you get into this more deeply, that she becomes really</p>
<p style="text-align: right;">83</p> <p>1 THE COURT: All right, thank you.</p> <p>2 MR. MONTGOMERY: Can I make one more point?</p> <p>3 THE COURT: Yes.</p> <p>4 MR. MONTGOMERY: When it comes to the Gaston</p> <p>5 affidavit, I think it's very important that your Honor apply</p> <p>6 to it a very exacting inquiry, and the reason is because if</p> <p>7 you lack back -- and I'm not suggesting you do because you'd</p> <p>8 have to become the Raiders of The Lost Ark -- but if you</p> <p>9 look back in the record, I think you'll find that the reason</p> <p>10 that you denied summary judgment, at least in part, is</p> <p>11 because the Department of Justice submitted an amicus brief</p> <p>12 to you, and that amicus brief said that FULs were set</p> <p>13 mechanically under the regulation. And what they told you,</p> <p>14 which certainly set up the basis for this order -- and they</p> <p>15 submitted the amicus brief just three or four weeks before</p> <p>16 you issued this order -- was not accurate. And then we</p> <p>17 fought for two years to get the discovery, and now we get</p> <p>18 this responsive affidavit. There is not a word in the</p> <p>19 affirmative papers supplied to you by these plaintiffs about</p> <p>20 Ms. Gaston. What you've got now is a responsive affidavit.</p> <p>21 And when you get a responsive affidavit on summary judgment,</p> <p>22 you need to look at it very carefully. If what they say</p> <p>23 about Ms. Gaston is accurate, then the affidavit is</p> <p>24 inconsistent with her testimony, and you should disregard it</p> <p>25 on that basis.</p>	<p style="text-align: right;">85</p> <p>1 the linchpin, the last gasp that they have to avoid summary</p> <p>2 judgment on causation grounds. And Ms. Gaston in her</p> <p>3 affidavit articulates this so-called three-WAC rule. And I</p> <p>4 won't go into exactly how it works except to say, and this</p> <p>5 is important, that Dr. Addanki in his report that he filed</p> <p>6 on June 30 -- I can give you a copy, and I can also give you</p> <p>7 the docket citation -- in Dr. Addanki's June 30 report, he</p> <p>8 takes the so-called three-WAC rule, and he applies it here</p> <p>9 to all of the NDCs at issue, and finds out it rarely was</p> <p>10 applied. And so --</p> <p>11 THE COURT: Unfortunately for everyone in this</p> <p>12 room, doesn't that create a question of fact that I can't</p> <p>13 resolve here?</p> <p>14 MR. MONTGOMERY: Not so, your Honor, because as I</p> <p>15 said --</p> <p>16 THE COURT: She says one thing, he says another.</p> <p>17 MR. MONTGOMERY: No, no, no. I think it's a</p> <p>18 matter of burden of proof, your Honor. I do not think that</p> <p>19 on this record the plaintiffs can possibly make out a case</p> <p>20 of causation. There is no dispute of fact. They haven't</p> <p>21 disputed what Dr. --</p> <p>22 THE COURT: Does she testify about this so-called</p> <p>23 three-WAC rule?</p> <p>24 MR. MONTGOMERY: She testifies about the three-WAC</p> <p>25 rule. All we're saying is, the three-WAC rule, even if</p>

<p style="text-align: right;">86</p> <p>1 she's testifying in good faith, even if she believes that</p> <p>2 the three-WAC rule is her mode of operation, she didn't tell</p> <p>3 us about it in her deposition, and in fact it --</p> <p>4 THE COURT: I thought you said she did.</p> <p>5 MR. MONTGOMERY: No, no, Gaston did testify in</p> <p>6 a -- she was deposed. So she's articulated a so-called</p> <p>7 rule, let's assume in good faith, that in fact isn't</p> <p>8 applied. That inconsistency, because she must have had</p> <p>9 Dr. Addanki available, you know, access to Dr. Addanki's</p> <p>10 information about how all of this worked, that inconsistency</p> <p>11 is something as a summary judgment matter that you ought to</p> <p>12 scrutinize. Witnesses can't come along in response in</p> <p>13 summary judgment and pose new issues, articulate new rules</p> <p>14 that are inconsistent with the facts, without explaining</p> <p>15 themselves.</p> <p>16 THE COURT: I thought she was deposed.</p> <p>17 MR. PALERMO: Your Honor, I'm sorry. Chris</p> <p>18 Palermo. Can I clarify?</p> <p>19 THE COURT: Yes.</p> <p>20 MR. PALERMO: Do you want me to try to clarify, at</p> <p>21 least? It's my understanding that Ms. Gaston did testify,</p> <p>22 but at her deposition did not mention the three-WAC rule,</p> <p>23 and that it was mentioned in her subsequent declaration.</p> <p>24 MR. MONTGOMERY: Yes, that's my point, your Honor.</p> <p>25 She was deposed in this case. She did not mention the</p>	<p style="text-align: right;">88</p> <p>1 you're referring to.</p> <p>2 MR. MONTGOMERY: One more point.</p> <p>3 THE COURT: Wait a minute, hold on. I tell you</p> <p>4 what, just let her finish her sentence and --</p> <p>5 MS. CICALA: Thank you, your Honor very much.</p> <p>6 THE COURT: Just on that point, and then I'll let</p> <p>7 you respond. So somebody could flip through the deposition.</p> <p>8 MS. CICALA: There's nothing whatsoever</p> <p>9 inconsistent between the declaration and the deposition.</p> <p>10 What the declaration adds, your Honor, is that Ms. Gaston</p> <p>11 offers the exact information your Honor was referring to</p> <p>12 earlier: What would she have done were she presented with</p> <p>13 an array with accurate prices from these defendants?</p> <p>14 THE COURT: But the way she calculated it is in</p> <p>15 the deposition?</p> <p>16 MS. CICALA: Yes.</p> <p>17 THE COURT: All right, thank you. Just finish up</p> <p>18 because it's getting late.</p> <p>19 MR. MONTGOMERY: Your Honor, if you look at her</p> <p>20 affidavit, what she says throughout is, "I might have done</p> <p>21 A, I might have done B." When she gets to the three-WAC</p> <p>22 rule, she said, "If there were different prices --" she does</p> <p>23 not talk about an array -- she talks about one or two, or</p> <p>24 two, I guess -- and she says, "I would have considered them</p> <p>25 and would have used one of them to set the FUL, provided I</p>
<p style="text-align: right;">87</p> <p>1 three-WAC rule. She then mentions the three-WAC rule in her</p> <p>2 affidavit. But, most importantly, regardless of when she</p> <p>3 mentioned it, the three-WAC rule, just like the FUL</p> <p>4 regulation, isn't applied. It doesn't work. And there's no</p> <p>5 dispute about it. So you've got --</p> <p>6 THE COURT: You think she mentions it in the</p> <p>7 deposition?</p> <p>8 MS. CICALA: Ms. Gaston's testimony in her</p> <p>9 deposition -- your Honor will read the deposition, I'm sure.</p> <p>10 The testimony in the deposition is entirely consistent with</p> <p>11 the declaration.</p> <p>12 THE COURT: But does it refer to the three-WAC</p> <p>13 rule?</p> <p>14 MS. CICALA: It refers to the procedure, which is</p> <p>15 the same procedure in the declaration, which is that she</p> <p>16 works her way up through the array to make sure that there</p> <p>17 are two WACs higher than the FUL that she sets.</p> <p>18 THE COURT: And that's in the deposition?</p> <p>19 MS. CICALA: Yes, and it's absolutely in the</p> <p>20 deposition. There's nothing inconsistent whatsoever between</p> <p>21 the approach applied --</p> <p>22 THE COURT: So what you're going to do, you're</p> <p>23 going to just e-mail Mr. Alba the pages?</p> <p>24 MS. CICALA: We will, we will. May I respond --</p> <p>25 THE COURT: Just to make sure they know what</p>	<p style="text-align: right;">89</p> <p>1 was able to determine that the price was valid and the</p> <p>2 product was widely available in the marketplace as described</p> <p>3 above."</p> <p>4 If you then look above or look at her deposition,</p> <p>5 what she's talking about is, she's going to do the market</p> <p>6 research that they did in every single instance. Medicaid,</p> <p>7 CMS here, your Honor, is like the PBMs that you called the</p> <p>8 800-pound gorillas. They have MACs. This is a MAC. The</p> <p>9 PBMs used AWP's and WACs to set their MACs, but they also had</p> <p>10 market intelligence. You declined to certify a class. It's</p> <p>11 just a perspective point, your Honor. It's --</p> <p>12 THE COURT: Just one last thing. Suppose I think</p> <p>13 it's likely that FULs would have been lower, but there's</p> <p>14 absolutely no possibility of figuring out what they would</p> <p>15 have been. Do you agree, putting aside the</p> <p>16 government-knowledge defense for a minute, do you agree that</p> <p>17 you don't have to get to the issue of whether it's even</p> <p>18 possible to calculate actual damages as part of this summary</p> <p>19 judgment motion? In other words, what if I found it's</p> <p>20 impossible to calculate actual damages, is that part of the</p> <p>21 cause of action at this point? Like, in antitrust, you have</p> <p>22 to say measurable damages -- I forget what it is -- there</p> <p>23 has to be an antitrust violation, there has to be an injury,</p> <p>24 and then you have to have measurable damages, or something</p> <p>25 like that. In this, it looks as if they've said, if there's</p>

<p style="text-align: right;">90</p> <p>1 a violation, then you get to damages.</p> <p>2 MR. MONTGOMERY: I don't see how you have</p> <p>3 causation if that's what you conclude.</p> <p>4 THE COURT: But what if you know it's likely to be</p> <p>5 lower, but you just don't know how much lower, where does</p> <p>6 that leave me?</p> <p>7 MR. MONTGOMERY: Well, I think it leaves you in</p> <p>8 the land of speculation.</p> <p>9 THE COURT: Even though you find it's likely to be</p> <p>10 a lower FUL, it's just, given the discretionary practices</p> <p>11 that are being followed, you can't figure out how much.</p> <p>12 MR. MONTGOMERY: Well, certainly, your Honor, you</p> <p>13 couldn't say that it would likely to be lower in every</p> <p>14 single instance. There's no pattern here. You couldn't --</p> <p>15 you couldn't from the existence of AMPs conclude what the</p> <p>16 FUL would have been in any single instance. You know, if</p> <p>17 you were to conclude contrary to what we think is</p> <p>18 appropriate that FULs may have been lower on an overall</p> <p>19 basis, they may have been lower on an occasional basis, it</p> <p>20 doesn't get you to a violation of this statute because</p> <p>21 you're only going to get there by talking about what all</p> <p>22 defendants might have done. You're really getting into the</p> <p>23 land of, you know, enterprise liability, joint and several</p> <p>24 liability. We've done no discovery on any relationship</p> <p>25 between the defendants. We don't have all the defendants</p>	<p style="text-align: right;">92</p> <p>1 do this, it's such a huge record, and it's going to be a</p> <p>2 huge amount of time just to rule on it --</p> <p>3 MS. CICALA: Well, the issue of damages was raised</p> <p>4 by defendants. Defendants make the damages argument in</p> <p>5 their brief without any support, your Honor, and we address</p> <p>6 it --</p> <p>7 THE COURT: It just seems like any damage figure</p> <p>8 is speculative at this point.</p> <p>9 MS. CICALA: Well, not any, your Honor. We've got</p> <p>10 situations where simple rules were applied in the old world,</p> <p>11 and simple rules can be applied in the new world.</p> <p>12 THE COURT: Maybe.</p> <p>13 MS. CICALA: And we are very comfortable going</p> <p>14 down this road and presenting your Honor with a rational,</p> <p>15 fair approach to dealing with the damage scenarios here.</p> <p>16 And as I said earlier, it may be joint and several, or there</p> <p>17 may be mitigating factors that defendants' WACs were ignored</p> <p>18 in the old world and would have been ignored again. That</p> <p>19 may be a mitigation issue. And that's where all of</p> <p>20 Dr. Addanki's comments about discretion come into play.</p> <p>21 THE COURT: All right, well, thank you. I don't</p> <p>22 know. I'm sorry, it's been very, very helpful.</p> <p>23 Who's here from the Department of Justice? All</p> <p>24 right. Oh, you've now moved up to the front bench, okay.</p> <p>25 (Laughter.)</p>
<p style="text-align: right;">91</p> <p>1 before you. It's really just not a part of it.</p> <p>2 THE COURT: Thank you very much.</p> <p>3 MR. MONTGOMERY: Thank you, your Honor.</p> <p>4 THE COURT: A quick response, and then I want to</p> <p>5 ask the government something.</p> <p>6 MS. CICALA: Yes, okay. Your Honor, all these</p> <p>7 comments about discretion do not go to the issue of</p> <p>8 liability at all. They go to the issue of damages entirely.</p> <p>9 The violation -- if, for example, defendants had reported</p> <p>10 WACs that were actually too low, okay, it's not that their</p> <p>11 WACs were overstatements but in fact their true WACs were</p> <p>12 higher than what they reported, they still would have</p> <p>13 violated 145-b, 1-B. We would still have a violation. It's</p> <p>14 a discrete portion of the statute. There is no nexus</p> <p>15 between those two provisions, okay? If we have a</p> <p>16 Laverdiere/Hillmon situation, right, the fraud just didn't go</p> <p>17 right, they still violated the statute. The next question</p> <p>18 is, once you have the violation, then you ask how much is</p> <p>19 the damage?</p> <p>20 THE COURT: The reason I keep asking this is</p> <p>21 because I have spoken to the mediator in this case, and I</p> <p>22 know this is a critical issue for all of you. I mean, I do</p> <p>23 know, and I need to resolve it, or it's like a holdup at</p> <p>24 this point. I don't know if that's true, but it's my sense</p> <p>25 of what it is. Once I rule, and it will take me a while to</p>	<p style="text-align: right;">93</p> <p>1 THE COURT: So here's my question, and I know</p> <p>2 you're a litigant so it's not quite as pure as when I, I</p> <p>3 think, asked last time. I think there was a misimpression</p> <p>4 from the Department of Justice in the last amicus brief, and</p> <p>5 I wanted to know if you wanted to submit another one.</p> <p>6 MR. FAUCI: If the Court thinks it would be</p> <p>7 helpful, I think the Department of Justice would be willing</p> <p>8 to do that, your Honor.</p> <p>9 THE COURT: Well, how about CMS, would you be</p> <p>10 doing it on their behalf? Is that it?</p> <p>11 MR. FAUCI: I'm sure we would, your Honor.</p> <p>12 THE COURT: The problem I run into is that you've</p> <p>13 now got something on the record that's just wrong.</p> <p>14 MR. FAUCI: And, quite frankly, the amicus brief,</p> <p>15 it was written before I was on the case, and it's not</p> <p>16 consistent with Ms. Gaston's or Ms. Sexton's testimony. I</p> <p>17 think it's probably obvious that the FUL-setting process was</p> <p>18 not mechanistic in any way. So if your Honor would think it</p> <p>19 would be helpful for an additional briefing, in light of</p> <p>20 Ms. Gaston's and Ms. Sexton's testimony, the department</p> <p>21 would be happy to do it.</p> <p>22 THE COURT: Or at the very least, because that's</p> <p>23 what's in the record, you need to either revoke the memo or</p> <p>24 explain, at least, the government's position, not on the</p> <p>25 law, the law of New York -- you don't have any particular</p>

<p style="text-align: right;">94</p> <p>1 say in that -- but on what happened here, because I, when I</p> <p>2 read this the first time through, I have to tell you was</p> <p>3 surprised because our working assumption was that it was a</p> <p>4 mandatory rule with a mandatory formula; and that just I</p> <p>5 think the defendants have very well proven is wrong. I</p> <p>6 mean, I think it was worth this exercise.</p> <p>7 MR. FAUCI: Does your Honor have a time frame on</p> <p>8 when this motion would --</p> <p>9 THE COURT: Not a motion. I don't want a motion.</p> <p>10 MR. FAUCI: Not a motion, I'm sorry. Piece of</p> <p>11 paper.</p> <p>12 THE COURT: I'm just giving you an option of</p> <p>13 revoking that amicus brief, or at least setting forth the</p> <p>14 Federal government's position as to what happened during</p> <p>15 this period of time; not giving an opinion on New York law,</p> <p>16 not giving an opinion on New York law because that's not</p> <p>17 special here, and based on this record, not something</p> <p>18 different.</p> <p>19 MR. FAUCI: I think the department would be happy</p> <p>20 to do that. The only thing I would just add is, we're</p> <p>21 opposing summary judgment motions in the federal intervenor</p> <p>22 cases due July 24, and so, frankly, if we could --</p> <p>23 THE COURT: Pick a date. This is so complex and</p> <p>24 so long that it's likely to be a six-month process.</p> <p>25 MR. FAUCI: I think anytime in mid to late August</p>	<p style="text-align: right;">96</p> <p>1 Honor. There is no dispute.</p> <p>2 MS. CICALA: As to discretion.</p> <p>3 THE COURT: I don't know that. I do know this,</p> <p>4 which is, I always want to hear from the federal government</p> <p>5 interpreting its own regulations and its own policies and</p> <p>6 practices. But in fairness, you limited discovery in this</p> <p>7 case, not you personally but the government did, you know,</p> <p>8 with all the valid Touhy regulations and this, that, and the</p> <p>9 other thing, so it can't be stuff that's outside the record.</p> <p>10 MR. FAUCI: Thank you.</p> <p>11 MS. CICALA: Your Honor, if I may, with all</p> <p>12 respect to Mr. Montgomery, my description of the number of</p> <p>13 depositions that occurred as far as I know is accurate.</p> <p>14 It's not just two witnesses. Mr. Reed was deposed, who was</p> <p>15 Ms. Gaston and Ms. Sexton's supervisor. So I'm not sure</p> <p>16 what Mr. Montgomery is referring to when he says there are</p> <p>17 only two witnesses.</p> <p>18 THE COURT: All right, that's fair enough. Just</p> <p>19 limited to our record.</p> <p>20 MS. CICALA: Thank you.</p> <p>21 THE COURT: It should be limited to our record.</p> <p>22 So that would be very useful. Are some of the -- I hate to</p> <p>23 say this, but you have a general counsel in place at the</p> <p>24 Department of Health and Human Services?</p> <p>25 MR. FAUCI: There are agency counsel on it.</p>
<p style="text-align: right;">95</p> <p>1 we could get you something.</p> <p>2 THE COURT: Fine.</p> <p>3 MR. MONTGOMERY: Your Honor just made the point</p> <p>4 that whatever they submit, if anything, ought to be based on</p> <p>5 this record.</p> <p>6 THE COURT: This record.</p> <p>7 MR. MONTGOMERY: I think it is critically</p> <p>8 important that if they have any disagreement with</p> <p>9 Dr. Addanki's analysis, they need to say so because, as I</p> <p>10 have said at some length, the Gaston affidavit is</p> <p>11 inconsistent in reality with what they do.</p> <p>12 THE COURT: I know that's your position. I</p> <p>13 just --</p> <p>14 MR. MONTGOMERY: Well, but it's not been disputed</p> <p>15 by plaintiffs, and so --</p> <p>16 MS. CICALA: Excuse me. I'm sorry, that's not</p> <p>17 accurate. What's not disputed by us?</p> <p>18 MR. MONTGOMERY: You're not disputing Addanki's</p> <p>19 analysis.</p> <p>20 MS. CICALA: No. The exercise of discretion?</p> <p>21 MR. MONTGOMERY: That's right.</p> <p>22 MS. CICALA: Well, I'm not willing to -- I do not</p> <p>23 embrace the entirety of Dr. Addanki's analysis. We agree as</p> <p>24 we have in our papers --</p> <p>25 MR. MONTGOMERY: There's a record here, your</p>	<p style="text-align: right;">97</p> <p>1 THE COURT: All right. And there is a head of the</p> <p>2 Centers for Medicare and Medicaid Services?</p> <p>3 MR. FAUCI: The agency counsel, but it is HHS.</p> <p>4 THE COURT: So we have people -- I understand that</p> <p>5 we're in a transition and not all positions have been</p> <p>6 filled. You're in a position to take a position for the</p> <p>7 federal government?</p> <p>8 MR. FAUCI: I would assume so.</p> <p>9 THE COURT: All right. We certainly have an</p> <p>10 Attorney General, so that we know.</p> <p>11 MR. PALERMO: Your Honor, if I may, just one</p> <p>12 point. There seems to be an assumption in a lot of the</p> <p>13 questioning that dominates today that the defendants have</p> <p>14 not reported truthful WACs, and I want the record to be</p> <p>15 clear that the defendants, my clients, Dey and the Mylan</p> <p>16 defendants, don't concede that at all.</p> <p>17 THE COURT: I understand.</p> <p>18 MR. PALERMO: All right, okay. I mean, at all</p> <p>19 times they reported truthful WACs consistent with the</p> <p>20 federal definition of WAC.</p> <p>21 THE COURT: You know what, you chose to sit way</p> <p>22 back there.</p> <p>23 MR. PALERMO: I just wanted to make the point for</p> <p>24 the record, your Honor, so that it was clear.</p> <p>25 THE COURT: You've made the record, okay, but at</p>

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1 this point it's been a long day and --

2 MR. PALERMO: Thank you, your Honor.

3 MS. CICALA: A quick question about the Daubert,
4 your Honor.

5 THE COURT: Can I tell you, you heard the word
6 "Neurontin" come up here?

7 MS. CICALA: I know you've had a long day.

8 THE COURT: I'm starting trial July 27. I've had
9 maybe five or six Daubert motions in that case alone. I
10 can't get to this before then.

11 MS. CICALA: It's not our motion, your Honor.
12 It's defendants' motion. We're opposing it, obviously. I
13 just ask whether your Honor would anticipate a hearing on
14 that?

15 THE COURT: I haven't even, candidly, read it.

16 MS. CICALA: Okay, fair enough.

17 THE COURT: Okay? So at some point I always have
18 a hearing on Daubert motions.

19 MS. CICALA: Thank you.

20 THE COURT: Whether it's evidentiary or not we can
21 talk about, but I always have a hearing on Daubert motions.

22 MS. CICALA: Very good. That is our practice too.
23 Thank you, your Honor.

24 THE COURT: Thank you.

25 (Adjourned, 4:35 p.m.)

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1 C E R T I F I C A T E

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4 UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

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7 I, Lee A. Marzilli, Official Federal Court
8 Reporter, do hereby certify that the foregoing transcript,
9 Pages 1 through 98 inclusive, was recorded by me
10 stenographically at the time and place aforesaid in Civil
11 Action No. 01-12257-PBS, In Re: Pharmaceutical Industry
12 Average Wholesale Price Litigation, and thereafter by me
13 reduced to typewriting and is a true and accurate record of
14 the proceedings.

15 In witness whereof I have hereunto set my hand
16 this 13th day of July, 2009.

17

18

19

20

21 /s/ Lee A. Marzilli

22 LEE A. MARZILLI, CRR
23 OFFICIAL FEDERAL COURT REPORTER
24
25